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IN THE

Supreme Court of the United States

OCTOBER TERM, 1976

No. 76-1250

VELSICOL CHEMICAL CORPORATION, *Petitioner,*

v.

ENVIRONMENTAL PROTECTION AGENCY, *et al.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Velsicol Chemical Corporation petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit affirming the order of the Administrator of the Environmental Protection Agency.

OPINIONS BELOW

The principal opinion of the Court of Appeals (App. A, Pet. App. 1-25),[1] and its "Supplemental

[1] "Pet. App." refers to the appendix to the petition, which is bound in a separate volume because of its unusual length.

Opinion on [Velsicol's] Petition for Rehearing" (App. B, Pet. App. 26-39) are not yet reported. The recommended decision of the Administrative Law Judge (App. D, Pet. App. 42-135) is reported in 41 Fed. Reg. 7555 (February 19, 1976). The decision of the Administrator of the Environmental Protection Agency (App. E, Pet. App. 136-208) is reported in 41 Fed. Reg. 7572 (February 19, 1976).

JURISDICTION

The judgment of the Court of Appeals (App. C, Pet. App. 40-41) was entered on November 10, 1976. A timely petition for rehearing was denied on January 6, 1977. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether § 7(c) of the Administrative Procedure Act ("APA"), 5 U.S.C. 556(d), which places the "burden of proof" on "the proponent of a rule or order," permits the Administrator of the Environmental Protection Agency ("EPA") to shift the "burden of persuasion" to the party opposing the Administrator's proposed order for suspension of a pesticide registration.

2. Whether § 6(c) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. 136d(c) (Supp. V, 1975), was intended by Congress to be a statute which shifted the "burden of proof" to the party opposing a suspension order.

STATUTORY PROVISIONS INVOLVED

The statutory provisions involved are reproduced as Appendix F, Pet. App. 209-224.

STATEMENT

This case involves the proper allocation of the "burden of proof" in administrative proceedings which can lead to an order by the Administrator of EPA suspending the registration of pesticides pursuant to § 6(c)(1) of FIFRA, 7 U.S.C. 136d (c)(1). In general, FIFRA provides that once a pesticide is "registered", it may be used for approved purposes until its registration is "cancelled", or is "suspended" pending the result of cancellation proceedings. 7 U.S.C. 136a. The Administrator can initiate proceedings to cancel a registration if he finds that the pesticide "generally causes unreasonable adverse effects on the environment", in which case the registrant is entitled to a plenary hearing. 7 U.S.C. 136d(b); 7 U.S.C. 136d(d).[2] If the Administrator finds that it "is necessary to prevent an imminent hazard during the time required for cancellation . . . proceedings", he may issue a suspension order which becomes effective only after an abbreviated and expedited hearing. 7 U.S.C. 136d(c)(1), (c)(2). Where the Administrator finds that "an emergency exists that does not permit him to hold a hearing before suspending," the Administrator may issue an emergency suspension order which takes effect immediately. 7 U.S.C. 136d (c)(3).

On November 18, 1974, the Administrator issued a notice of intent to cancel the registrations of chlordane and heptachlor, two pesticides produced by Velsicol. During the pendency of these cancellation

[2] Cancellation occurs automatically at the end of the 5 year registration period unless the registrant makes a request to continue the registration. 7 U.S.C. 136d(a).

proceedings, on July 29, 1975, the Administrator initiated a separate proceeding for a non-emergency *suspension* of these same pesticides pending the conclusion of the cancellation proceedings.

Pursuant to the administrative procedures required by statute for § 6(c)(1) suspensions, the petitioner was notified of the Administrator's proposed suspension order and given 5 days to request a hearing.[3] Velsicol made a timely request for a hearing on the Administrator's proposed suspension order. Pursuant to the statute which requires that the hearing commence within 5 days of the registrant's request,[4] prehearing conferences were held on August 6, 7 and 11, 1975, and the hearing before the Administrative Law Judge ("ALJ") was commenced on August 12, 1975.

The ALJ conducted the hearing pursuant to EPA's rule which places "the ultimate burden of persuasion" on the registrant opposing the suspension order. 40 C.F.R. § 164.121(g) (1975). On December 12, 19[illegible] after 43 days of hearing, the ALJ issued his recommended decision. He recommended dismissal of the notice of intention to suspend because he did not find that heptachlor and chlordane presented an "imminent hazard", within the meaning of the statute. Pet. App. 106-107, 135. On December 24, 1975, however, the Administrator purportedly accepted the ALJ's findings but overturned the ultimate conclu-

[3] Failure to request a hearing within the 5 day period permits the Administrator to issue the suspension order and forecloses the registrant from judicial review of the order. 7 U.S.C. 136d (c)(2).

[4] 7 U.S.C. 136d(c)(2).

sion[5] and suspended the registrations of the pesticides.[6] Pet. App. 139-140, 145, 199-203.

Velsicol petitioned for review of the Administrator's suspension order pursuant to 7 U.S.C. 136d (c)(4).[7] Velsicol challenged the Administrator's order on both substantive and procedural grounds, including the allocation of the "burden of proof". In its decision of November 10, 1976, the Court of Appeals essentially affirmed the Administrator's order. With respect to the "burden of proof" issue, the court ruled that EPA's allocation of the "burden of persuasion" to the registrant was consistent with Section 7(c) of the APA, 5 U.S.C. 556(d). Pet. App. 8-10.

Velsicol filed a timely petition for rehearing and suggestion for rehearing *en banc* arguing *inter alia* that the panel's ruling on the pivotal "burden of proof" issue had adopted a theory never briefed or

[5] The Administrator both brings the charges (contained in the notice of intent to suspend) and ultimately adjudicates whether they have been sustained. 7 U.S.C. 136d(c)(1); 7 U.S.C. 136d(d).

[6] The Administrator excluded a number of uses of the pesticide from the suspension order, finding that the benefits from these uses outweighed the risks. This portion of the Administrator's order, affirmed by the Court of Appeals, is of course not challenged by petitioner Velsicol.

[7] Velsicol's petition for review, originally filed in the Sixth Circuit, was transferred to the United States Court of Appeals for the District of Columbia Circuit and there consolidated with petitions filed by the Secretary of Agriculture and the Environmental Defense Fund ("EDF"). The Secretary sought the same relief as Velsicol while EDF sought review of the Administrator's decision to suspend only certain uses of the pesticides. Velsicol was an intervenor with respect to the Secretary's and EDF's petitions. Pet. App. 3-4.

argued by the parties.[8] While apparently acknowledging Velsicol's point, the Court of Appeals denied rehearing and issued a "Supplemental Opinion On Petition for Rehearing". App. B. The "Supplemental Opinion" reaffirmed the panel's original interpretation of § 7(c) of the APA finding that the "burden of proof" in the APA meant "burden of going forward rather than the burden of ultimate persuasion". Pet. App. 28. The court then advanced an alternate ground which had not been discussed in the original decision: the panel found that even if the APA would normally place the "burden of persuasion" on the agency, suspension hearings under FIFRA fell within the exception in § 7(c) of the APA in which the burden was "otherwise provided by statute."

REASONS FOR GRANTING THE WRIT

The writ should be granted to resolve the important question of the proper allocation of the "burden of proof" under § 7(c) of the Administrative Procedure Act, 5 U.S.C. 556(d). The significance of this question derives from the general applicability of the APA to virtually all federal agencies and from the fact that the allocation of the "burden of proof" will unquestionably have a substantial impact on the result of the administrative hearings affected. While it cannot be said that the Circuits are in direct conflict on the point, the approach adopted by the court below is analytically in-

[8] Neither the EPA nor the EDF had even attempted to defend EPA's regulation based upon the distinction between "burden of proof" and "burden of persuasion," which the Court of Appeals found to be crucial.

consistent with prior decisions of the Fifth [9] and Ninth Circuits [10] which have placed the burden on the proponents of orders without distinguishing between the "burden of proof" and the "burden of persuasion" in interpreting the APA. The decision below is also contrary to the interpretation accepted by the Second Circuit in *Kerner* v. *Flemming,* 283 F.2d 916, 921-22 (2d Cir., 1960) (Friendly, J.). The need for review by this Court is underscored by the continuing uncertainty on this point. *See, e.g.,* the divergent opinions in *Old Ben Coal Corp.* v. *Interior Board of Mine Operations Appeals,* 523 F.2d 25 (7th Cir., 1975).

The alternate holding of the Court of Appeals, interpreting § 6(c) of FIFRA, also has substantial significance because of its impact on the availability of pesticides which are essential to the agricultural economy. A clear indication of the importance of the pesticides involved here is the fact that the Secretary of Agriculture, who has been charged by statute with special responsibilities in this area, [11] also petitioned for review of the Administrator's suspension order. See Pet. App. 3-4.

1. The Court of Appeals erred in concluding that the Administrative Procedure Act permits the "burden of persuasion" to be placed upon Velsicol, the party *op-*

[9] *N.L.R.B.* v. *Atlanta Coca-Cola Bottling Company,* 293 F.2d 300, 309 (5th Cir.), *rehearing denied,* 296 F.2d 896 (1961).

[10] *United States* v. *Springer,* 491 F.2d 239, 242 (9th Cir.), *cert. denied,* 419 U.S. 834 (1974); *Kirby* v. *Shaw,* 358 F.2d 446, 449 (9th Cir., 1966).

[11] See 7 U.S.C. 136d(b) (Supp. V, 1975) (Pet. App. 221-23). The Secretary intervened as a party in the administrative proceedings below, and opposed suspension of the registrations.

posing the suspension order.[12] Section 7(c), of the APA, 5 U.S.C. 556(d), states:

> Except as otherwise provided by statute, *the proponent of a rule or order has the burden of proof* . . . (emphasis supplied).

In view of the plain and direct statutory language, the Court of Appeals' conclusion can be sustained only if the legislative history (i) explicitly distinguishes between the "burden of proof" and the "burden of persuasion" and (ii) establishes that Congress intended that the "burden of persuasion" could be placed upon the *opponent* of an order. The legislative history does not support this distinction and certainly does not indicate that the burden was to shift. To the contrary, the legislative history demonstrates that Congress considered and rejected the construction adopted by the court below.

The Senate Report, upon which the Court of Appeals places principal reliance,[13] does not recognize this distinction nor does it even suggest that the *opponent* of an order would have the "burden of persuasion." The Senate Report merely states that "parties [other than the party initiating the proceeding] who are proponents of some *different result,* also for *that purpose* have a

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[12] FIFRA clearly designates the Administrator to be the proponent of the order:

> If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, he may, *by order,* suspend the registration of the pesticide immediately . . .

7 U.S.C. 136d(c)(1) (emphasis supplied).

[13] S. Rep. No. 752, 79th Cong., 1st Sess. 22 (1945), *reprinted* in S. Doc. 248, 79th Cong., 2d Sess. at 208 (1946).

burden to maintain" (emphasis supplied). The Report stands for the common-sense proposition that any party who seeks a substantive modification of a proposed order must bear the same burden of proof with respect to the modification as the originating party does with respect to the original order. The House Report,[14] which the Court of Appeals believed "confirm[ed]" the Senate Report, states that "every proponent of a rule or order or the denial thereof has the burden of coming forward with *sufficient* evidence therefor" (emphasis supplied). The House Report makes no mention of the "burden of persuasion," and surely does not shift the burden to the party opposing the order. In short, neither Report even recognizes the "burden of persuasion" as distinct from the "burden of proof" and they surely do not compromise the plain statutory language which provides that "the proponent of a rule or order has the burden of proof."

More illuminating is the change in the prior drafts of the APA, and the accompanying legislative history, which clearly indicate that Congress considered and ultimately rejected the interpretation of "burden of proof" adopted by the Court of Appeals. An earlier version of S. 7 provided,[15]

> The proponent of a rule or order shall have the *burden of proceeding* except as statutes otherwise provide.
>
> S. Doc. 248, supra, at 11, 158, (emphasis supplied).

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[14] H.R. Rep. 1980, 79th Cong., 2d. Sess. at 34 (1946), *reprinted* in S. Doc. 248, *supra,* at 270.

[15] S. 7 and its analog in the House of Representatives, H.R. 1203, were the bills which were amended and ultimately enacted as the APA. See S. Doc. 248, *supra,* at 11.

The Senate Judiciary Committee revised S. 7 to read:

> Except as statutes otherwise provide, the proponent of a rule or order shall have the *burden of proof*.
>
> S. Doc. 248, *supra,* at 30 (emphasis supplied.)[16]

Explaining this modification of the statutory language, the Senate Judiciary Committee stated:

> The provision relating to burden of proof is the standard rule.
>
> S. Doc. 248, supra, at 31.

The only interpretation of § 7(c) which is consistent with the statutory language, and with this legislative history, is that the Administrator as the proponent of the suspension order bears the "burden of proof"; and that the "burden of proof" encompasses the "burden of persuasion", not merely the "burden of proceeding" or going forward.

2. While the second issue, involving an interpretation of FIFRA is one of lesser overall significance, it nevertheless constitutes an extremely important question for the producers and users of agricultural pesticides. The court below was clearly wrong in its alternate holding that § 6(c)(1) of FIFRA was intended to allocate the burden of proof to the opponent of a suspension order.[17] The logic of the statutory framework established by the 1972 amendments to FIFRA and the incorporation of the APA "burden of proof" provision into the suspension section demon-

[16] With respect to the portion at issue here, the language ultimately approved by the Senate Judiciary Committee is identical to 5 U.S.C. 556(d).

[17] In response to Velsicol's petition for rehearing, the court below held for the first time that suspension orders fell into the exception in § 7(c) of the APA.

strate that Congress intended to dispel any doubt that the burden in *suspension* proceedings, unlike registration or cancellation proceedings, was to be on the Administrator.

The 1964 version of FIFRA placed the burden of proof on the registrant both in registration and in cancellation proceedings. *Stearns Electric Paste Corp. v. EPA,* 461 F.2d 293 (7th Cir., 1972). However, *Stearns* conspicuously did *not* place the burden of proof on the registrant in *suspension* proceedings though it explicitly noted that the registrant must shoulder the burden in the other proceedings involving registrants (namely initial registration, refusal to re-register, and all cancellation proceedings). 461 F.2d at 305, n. 38. Shortly after *Stearns* was decided, Congress specifically addressed this question in the 1972 amendments to FIFRA[18] which revised the statutory procedures for suspension orders by (i) requiring the expedited hearing procedures involved here,[19] (ii) eliminating the advisory committee procedures[20] *only* for suspension hearings, and (iii) subjecting *only* the suspension hearings to the requirements of the APA.[21] 7 U.S.C. 136d(c)(2).

The statutory framework established by the 1972 amendments makes perfect sense. It does not incorpo-

[18] P.L. 92-516, 86 Stat. 973 (1972).

[19] See pp. 4-5, *supra.*

[20] Compare 7 U.S.C. 135b(c) (1970 ed.) (Pet. App. 211-15) with 7 U.S.C. 136d(d) (Supp. V, 1975) (Pet. App. 220-21).

[21] 7 U.S.C. 136d(c)(2) provides in pertinent part:

> The [suspension] hearing shall be held in accordance with the provisons of subchapter II of chapter 5 of Title 5, except that the presiding officer need not be a certified hearing examiner.

rate the APA burden of proof provision in the sections of FIFRA covering registration and cancellation proceedings, in which the registrant has ample time to marshal the necessary evidence. 7 U.S.C. 136a(c); 7 U.S.C. 136d(a), 136d(b). However, the burden of proof is necessarily—and by express incorporation of the APA provision—placed upon the Administrator in *suspension* proceedings because the registrant has a maximum of 10 days notice to prepare for the suspension hearing, while the Administrator can muster all his evidence before initiating suspension proceedings.[22] For situations of true "emergency", Congress has authorized the Administrator to order immediate suspensions with hearings to follow. 7 U.S.C. 136d(c)(3).

Thus the evolution of FIFRA, and the present statutory scheme confirm that Congress intended that the Administrator have the burden of proof in suspension proceedings.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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[22] In suspension proceedings, the registrant also loses the right he had in the 1964 version of FIFRA to have scientific questions referred to a neutral advisory committee. *See* n.20, ***supra***.

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APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 75-2259

ENVIRONMENTAL DEFENSE FUND, INC., *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY AND
RUSSELL E. TRAIN, AIMINISTRATOR, *Respondents*
VELSICOL CHEMICAL CORPORATION
PINEAPPLE GROWERS ASSOCIATION OF HAWAII, ET AL.,
Intervenors

No. 76-1181

EARL L. BUTZ, SECRETARY OF AGRICULTURE
OF THE UNITED STATES, *Petitioner*

v.

RUSSELL E. TRAIN, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, *Respondent*
VELSICOL CHEMICAL CORPORATION, *Intervenor*

No. 76-1245

VELSICOL CHEMICAL CORPORATION, *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY,
RUSSELL E. TRAIN, ADMINISTRATOR, *Respondent*

No. 76-1247

VELSICOL CHEMICAL CORPORATION, *Petitioner*

v.

RUSSELL E. TRAIN, ADMINISTRATOR,
ENVIRONMENTAL PROTECTION AGENCY, *Respondent*

Petitions for Review of an Order of the
Environmental Protection Agency

Argued April 15, 1976

Decided November 10, 1976

Jacqueline M. Warren, with whom *William A. Butler* and *John F. Dienelt,* were on the brief for petitioner in No. 75-2259.

Raymond W. Fullerton, Attorney, with whom *James Michael Kelly,* Assistant General Counsel, *Alfred R. Nolting* and *Margaret M. Breinhalt,* Attorneys, Department of Agriculture, were on the brief for petitioners in No. 76-1181.

Robert L. Weinberg, with whom *John G. Kester, Richard M. Cooper* and *Kendra Heymann,* were on the brief for intervenor Velsicol Chemical Corp.

Michael H. Stein, Attorney, Department of Justice with whom *Rex E. Lee,* Assistant Attorney General, *Robert E. Kopp,* Attorney, Department of Justice *Robert V. Zenn,* General Counsel, Environmental Protection Agency, *Richard J. Denney Jr.,* Associate General Counsel, *John E. Bonine,* Deputy Associate General Counsel, *Lee C. Schroer*

and *Ronald C. Hausman,* Attorneys, Environmental Protection Agency, were on the brief for respondents.

Peter Barton Hutt and *Clausen Ely, Jr.,* were on the brief for intervenor, Pineapple Growers Association of Hawaii, et al.

Before: LEVENTHAL, ROBINSON and WILKEY, *Circuit Judges*

Opinion for the Court filed by *Circuit Judge* LEVENTHAL.

LEVENTHAL, *Circuit Judge*: This case involves the pesticides heptachlor and chlordane. Consolidated petitions seek review of an order of the Environmental Protection Agency (EPA) suspending the registration of those pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) [1] for certain uses. The Administrator of EPA issued an order on December 24, 1975. The order prohibited further production of these pesticides for the suspended uses, but permitted the pesticides' continued production and sale for limited minor uses. Even as to the suspended uses, the Order tempered its impact in certain respects: It delayed until August 1, 1976, the effective date of the prohibition of production for use on corn pests; and it permitted the continued sale and use of existing stocks of registered products formulated prior to July 29, 1975.

One petition to review was filed by Earl L. Butz, Secretary of Agriculture of the United States (U.S.D.A.). Secretary Butz and intervenor Velsicol Chemical Corporation, the sole manufacturer of heptachlor and chlordane, urge that the EPA order as to chlordane be set aside on both substantive and procedural grounds.[2] They contend that

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[1] 7 U.S.C. § 136 *et seq.* (Supp. V 1975).

[2] Velsicol has voluntarily ceased production of heptachlor for the uses suspended by the Administrator, and has not really attacked the Administrator's decision suspending those uses. USDA urges that this makes the heptachlor issues moot. Although we put

substantial evidence does not support the Administrator's conclusion that continued use of chlordane poses an imminent hazard"[3] to human health, and that the Administrator made critical errors in assessing the burden of proof and in weighing the benefits against the risks of continued use of chlordane.

The other petition, filed by Environmental Defense Fund, urges that the Order did not go far enough to protect against the hazards of heptachlor and chlordane use. EDF sought an injunction against the provisions permitting continued production and use of the pesticides on corn pests until August 1, 1976. EDF also challenges the Administrator's decision to allow continued use of the stocks of the two pesticides existing as of July 29, 1975,[4] contending that EPA should have provided for retrieval and controlled disposal of such stocks. EDF also contends that the Administrator erred in failing to suspend certain "minor uses" of chlordane and heptachlor.[5]

On the issue of retrieval of existing stocks, we remand for further consideration. In all other respects, we affirm the Administrator's Order. In view of our conclusion, we denied EDF's request for a stay pending appeal of the

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more emphasis on chlordane than heptachlor in this opinion, we cannot agree with USDA that voluntary cessation of production moots our consideration of the order of suspension as to heptachlor, since this voluntary acquiescence does not bind Velsicol; nor does it resolve the challenges EDF makes to EPA's failure to recall heptachlor stocks from the distributive chain and its refusal to suspend heptachlor's use on pineapples and for seed treatment.

[3] 7 U.S.C. § 136d(c)(1) (Supp. V 1975).

[4] July 29, 1975, was the day the Notice of Intent to Suspend was issued.

[5] The Pineapple Growers Association of Hawaii and the Attorney General and Department of Agriculture of the State of Hawaii also intervened to defend the decision to continue registration of one of the minor uses—control of ants on pineapples.

provision delaying the effective date for use on corn pests.[6] In effect, we approved the delay of effective date (as to corn) until August 1, 1976, and in this opinion we set forth our reasons for that conclusion. (Part II, B, 1)

I. Statutory Framework and Standard of Review

The issues posed by administrative action pursuant to FIFRA are not new to this court,[7] and we have previously extensively described the statutory framework for such actions. What is involved here is a suspension of registration of two pesticides during the pendency of the more elaborate cancellation of registration proceeding, initiated in this case by a November 18, 1974, notice of intent to cancel. This 1974 notice stated that there existed "substantial questions of safety amounting to an unreasonable risk to man and the environment" from continued use of heptachlor and chlordane. Public cancellation hearings pursuant to that notice were not expected to commence for some time.[8] On July 29, 1975, the Administrator issued a Notice of Intent to Suspend the registrations of most use of the two pesticides. The Administrator then commented on that expected delay in completing the cancellation hearings, and cited "new evidence . . . which confirms and heightens the human cancer hazard posed by

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[6] On February 13, 1976, EDF argued for a stay of the Administrator's Order permitting continued use of chlordane and heptachlor on corn until August 1, 1976; on February 17, 1976, this court deferred ruling on that motion until oral arguments on the merits. The motion for stay was denied April 16, 1976.

[7] *See* EDF v. EPA [Shell Chemical Co., et al.], 167 U.S. App. D.C. 71, 510 F.2d 1292 (1975); EDF v. EPA, 160 U.S. App. D.C. 123, 489 F.2d 1247 (1973); EDF v. EPA, 150 U.S. App. D.C. 348, 465 F.2d 528 (1972); EDF v. Ruckelshaus, 142 U.S. App. D.C. 74, 439 F.2d 584 (1971); Wellford v. Ruckelhaus, 142 U.S. App. D.C. 88, 439 F.2d 598 (1971).

[8] At the time the briefs in this case were filed, the hearings had still not begun in the cancellation proceeding.

these pesticides." On August 4, 1975, registrant Velsicol Chemical Corporation requested an expedited adversary hearing on the suspension question pursuant to § 6 of FIFRA, 7 U.S.C. § 136d(c). Administrative Law Judge Herbert L. Perlman presided over the cancellation hearings beginning August 12. Evidence was limited to human health issues and the benefits of continued use of heptachlor and chlordane. The record was closed December 4, 1975, and on December 12, the ALJ recommended against suspension, stating that he was unable to find that "heptachlor and chlordane are conclusively carcinogens in laboratory animals."[9] The Administrator reversed that decision on December 24, 1975, and suspended most uses of chlordane and heptachlor.

The Administrator is authorized to suspend the registration of a pesticide where he determines that an "imminent hazard" is posed by continued use during the time required for cancellation. Section 6(c) of FIFRA, 7 U.S.C. § 136d(c)(1). An "imminent hazard" exists where continued use during the time required for the cancellation proceeding would be likely to result in "unreasonable adverse effects on the environment." Section 2(l) of FIFRA, 7 U.S.C. § 136(l). The term "unreasonable adverse effects on the environment" is, in turn, defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Section 2(bb) of FIFRA, 7 U.S.C. § 136(bb).

As in our previous suspension case involving aldrin/dieldrin,[10] the primary challenge raised by Velsicol and USDA goes to the adequacy of the evidentiary basis of EPA's finding that the suspended pesticides present an

[9] ALJ Recommended Decision at 86.

[10] EDF v. EPA [Shell Chemical Co., et al.], 167 U.S. App. D.C. 71, 510 F.2d 1292 (1975).

imminent hazard during the time required for cancellation. The standard against which we test that challenge is defined in Section 16(b) of FIFRA:

> The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole.

The standard of substantial evidence has been defined as:[11]

> something less than the weight of the evidence . . . [T]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.

In applying this principle of review[12] in the specific context of a suspension of pesticides, this court has reiterated that "the function of the suspension decision is to make a preliminary assessment of evidence, and probabilities, not an ultimate resolution of difficult issues. We cannot accept the proposition . . . that the Administrator's findings . . . [are] insufficient because controverted by respectable scientific authority. It [is] enough at this stage that the administrative record contain[s] respectable scien-

[11] Consolo v. Federal Maritime Commission, 383 U.S. 607, 620 (1966).

[12] The problem of applying the substantial evidence standard to decisions made at the frontiers of scientific knowledge was commented on in Industrial Union v. Hodgson, 162 U.S. App. D.C. 331, 499 F.2d 467 (1974). *See generally* Note, *Judicial Review of the Facts in Informal Rulemaking*, 84 Yale L.J. 1750, 1760-68 (1975). Similar problems are presented in review under the arbitrary and capricious standard. *See, e.g.*, Amoco Oil Co. v. EPA, 163 U.S. App. D.C. 162, 501 F.2d 722 (1974).

tific authority supporting the Administrator." Environmental Defense Fund v. EPA [Shell Chemical Co., et al.], 167 U.S.App.D.C. 71, 77, 510 F.2d 1292, 1298 (1975) *quoting* Environmental Defense Fund v. EPA, 150 U.S. App. D.C. 348, 357, 465 F.2d 528, 537 (1972).

These decisions of our court also point out that the Administrator is not required to establish that the product is unsafe in order to suspend registration, since FIFRA places "[t]he burden of establishing the safety of a product requisite for compliance with the labeling requirements . . . at all times on the applicant and registrant."[13] Velsicol and USDA urge that this allocation of burden of proof relied on by the Administrator is inconsistent with the explicit terms of FIFRA. They rely on FIFRA's specific incorporation of subchapter II of the Administrative Procedure Act, which provides in relevant part that "Except as statutes otherwise provide, the proponent of a rule or order shall have the burden of proof." 5 U.S.C. § 556(d).

The EPA regulation governing the burden of proof in suspension proceedings provides:

> At the hearing, the proponent of suspension shall have the burden of going forward to present an affirmative case for the suspension. However, the ultimate burden of persuasion shall rest with the proponent of the registration. 40 C.F.R. § 164.121(g) (1975).

Assuming that the Administrator is the "proponent" of a suspension order and is governed by § 556(d), the legislative history of that provision indicates that it allocates the burden of going forward rather than the burden of ultimate persuasion and is consistent with the EPA's apportionment of burden:

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[13] EDF v. EPA, 167 U.S. App. D.C. at 76, 510 F.2d at 1297, *quoting* EDF v. EPA, 150 U.S. App. D.C. at 352, 465 F.2d at 532.

> That the proponent of a rule or order has the burden of proof means not only that the party initiating the proceeding has the general burden of coming forward with a prima facie case but that other parties, who are proponents of some different result, also for that purpose have a burden to maintain. S. Doc. No. 245, 79th Cong., 2d Sess. 208, 270 (1946).

This allocation of the burden of going foward[14] structures evaluation of the factual evidence adduced for both the Administrator and the reviewing court, and is consistent with the traditional approach that this burden normally falls on the party having knowledge of the facts involved.

In urging that the ultimate burden of proof in a suspension proceeding rests on the Administrator, Velsicol and USDA assert that the suspension decision is a drastic step differing fundamentally from both the registration and cancellation decisions made under FIFRA. Be we have already cautioned that the "imminent hazard" requisite for suspension is not limited to a concept of crisis: "It is enough if there is *substantial likelihood* that serious harm will be experienced during the year or two required in any realistic projection of the administrative process."[15]

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[14] *See also* NLRB v. Mastro Plastics Corp., 354 F.2d 170, 176 (2d Cir. 1965), *cert. denied,* 384 U.S. 972 (1966). In Stearns Electric Paste Co. v. EPA, 461 F.2d 293, 304 (7th Cir. 1972), Judge Stevens held that the 1964 amendments to FIFRA had shifted the burden of proof to the registrant "whether in a proceeding for initial registration or in a cancellation proceeding." In view of our decision that the EPA's allocation of burden of proof is consistent with the requirements of § 556(d), the 1972 general incorporation of APA standards into FIFRA did not operate to shift the ultimate burden of proof away from the registrant *sub silentio.*

[15] EDF v. EPA, 167 U.S. App. D.C. 71 at 76, 510 F.2d at 1297, quoting EDF v. EPA, 150 U.S. App. D.C. at 360, 465 F.2d at 540. Our en banc decision in Ethyl Corp v. EPA, —— U.S. App. D.C. ——, —— F.2d —— (1976), slip op. at 29, n.28, *cert. denied,* 44

"FIFRA confers broad discretion" on the Administrator to find facts and "to set policy in the public interest." Wellford v. Ruckelshaus, 142 U.S.App.D.C. 88, 91, 439 F.2d 598, 601 (1971). This broad discretion was conferred on the implicit assumption that interim action may be necessary to protect against the risk of harm to the environment and public health while a fuller factual record is developed in the cancellation proceeding. This avenue of protective relief would be effectively foreclosed if we accepted Velsicol's argument that the Administrator must *prove* imminent hazard [16]—apparently in some sense of weight of the evidence, going beyond substantial likelihood. But as we have already pointed out, the basic statutory directive requires affirmance of the Administrator's decision if supported by substantial evidence, and this requires "something less than the weight of the evidence." [17] We reject that renewed invitation to exercise increased substantive control over the agency decision process, and turn to a consideration of whether the Administrator's decision to suspend most uses of heptachlor and chlordane is supported by substantial evidence.

II. Substantial Evidence Support for the Administrator's Decision

To evaluate whether use of a pesticide poses an "unreasonable risk to man or the environment," the Administrator engages in a cost-benefit analysis that takes "into account the economic, social and environmental costs and

U.S.L.W. 3719 (U.S. June 14, 1974), considered this standard as more rigorous than the standard involved in *Ethyl;* we have not sought to engage in a comparative analysis of the differences that may be discernible in these two statutory standards, but have rested with applying the "substantial likelihood" standard to the facts of this case.

[16] Velsicol Br. at 31.

[17] See text at note 11.

benefits of the use of any pesticide." 7 U.S.C. § 136(bb). We have previously recognized that in the "preliminary assessment of probabilities" involved in a suspension proceeding, "it is not necessary to have evidence on . . . a specific use or area in order to be able to conclude on the basis of substantial evidence that the use of [a pesticide] in general is hazardous." EDF v. EPA, 160 U.S.App.D.C. at 130, 489 F.2d at 1254, *quoted in* EDF v. EPA [Shell Chemical Co.], 167 U.S.App.D.C. at 80, 510 F.2d at 1301. "Reliance on general data, consideration of laboratory experiments on animals, etc." has been held a sufficient basis for an order cancelling or suspending the registration of a pesticide. *Id.* Once risk is shown, the responsibility to demonstrate that the benefits outweigh the risks is upon the proponents of continued registration. Conversely, the statute places a "heavy burden" [18] of explanation on an Administrator who decides to permit the continued use of a chemical known to produce cancer in experimental animals. Applying these principles to the evidence adduced in this case, we conclude that the Administrator's decision to suspend most uses of heptachlor and chlordane and not to suspend others is supported by substantial evidence and is a rational exercise of his authority under FIFRA.

A. *Risk Analysis—Carcinogenicity of Heptachlor and Chlordane*

Velsicol and USDA contend that the laboratory tests on mice and rats do not "conclusively" demonstrate that chlordane is carcinogenic to those animals; that mice are too prone to tumors to be used in carcinogenicity testing in any case; and that human exposure to chlordane is insufficient to create a cancer risk. They place strong reliance

[18] 167 U.S. App. D.C. at 81, 510 F.2d at 1302, *quoting* EDF v. Ruckelshaus, 142 U.S. App. D.C. 74, 86 n.41, 439 F.2d 584, 596 n.41 (1971).

on the Administrative Law Judge's refusal to recommend suspension because he was "*hesitantly unwilling at this time* to find that heptachlor and chlordane are conclusively carcinogens in laboratory animals." Rec. Dec. at 86 (emphasis in original). The ALJ recognized however, that on the basis of the record made the Administrator "could determine that the pesticides involved pose potential or possible carcinogenic risk to man" and that he could "find that heptachlor and chlordane are conclusively carcinogenic in laboratory animals." [19] While adopting the ALJ's factual findings, the Administrator concluded that the ALJ had applied an erroneous legal standard in requiring a conclusive rather than probable showing that the pesticides were animal carcinogens, and concluded in any case that the evidence showed heptachlor and chlordane to be animal carcinogens. We affirm.

1. *Mice and Rat Studies*

An ultimate finding in a suspension proceeding that continued use of challenged pesticides poses a "substantial likelihood of serious harm" must be supported by substantial, but not conclusive, evidence. In evaluating laboratory animal studies on heptachlor and chlordane there was sufficient "respectable scientific authority" upon which the Administrator could rely in determining that heptachlor and chlordane were carcinogenic in laboratory animals.

We start by rejecting Velsicol's argument that the "cancer principles" EPA relied on in structuring its analysis of the mice and rate studies improperly biased the agency's open-minded consideration of the evidence.[20] In brief form,

[19] ALJ Recommended Decision at 86-87, n.25.

[20] Velsicol also claims that ex parte contact between the enforcements staff and the Acting Administrator on this point requires reversal of the suspension order. After having been contacted by the enforcement staff, the Acting Administrator issued a clarification of the July 29 Notice to Suspend which made clear that

the principles accept the use of animal test data to evaluate human cancer risks; consider a positive oncogenic effect in test animals as sufficient to characterize a pesticide as posing a cancer risk to man; recognize that negative results may be explained by the limited number and sensitivity of the test animals as compared to the general human population; note that there is no scientific basis for establishing a no-effect level for carcinogens; and view the finding of benign and malignant tumors as equally significant in determining cancer hazard to man given the increasing evidence that many "benign" tumors can develop into cancers. The Agency's reliance on these principles did not come as a surprise to Velsicol; they were included in the Administrator's Notice of Intent to Suspend; and as recognized in EDF v. EPA, 167 U.S.App.D.C. at 77-78, 510 F.2d at 1298-99, form part of the Agency's "scientific expertise." Velsicol was properly given an opportunity to put in evidence contesting those principles, but failed to demonstrate anything more than some scientific disagreement with respect to them. Velsicol's principal complaint —that mice are inappropriate test animals—was specifically rejected by the Administrator, citing statements by the National Academy of Sciences' Food Protection Committee, the World Health Organization, HEW's Commission on Pesticides and their Relationship Environmental

Velsicol could challenge the cancer principles during the suspension hearing. These facts do not require reversal. We have indicated that the prosecuting staff may consult with the agency head concerning the initiation of a second related proceeding or, where emerging evidence requires it, the broadening of an existing charge. Environmental Defense Fund, Inc. v. EPA, 167 U.S. App. D.C. 71, 84, 510 F.2d 1292, 1305 (1975). The consultations here, which were intended to aid the agency head in his function of framing charges, were of the same procedural type. While we are sensitive to the danger of abuse in such consultations, there was clearly no unfairness in the circumstances of this case, since the effect of the resulting order was simply to recognize the registrant's right to present additional evidence.

Health, FDA Advisory Panel on Carcinogenesis, International Agency for Research on Cancer, and Director of the National Cancer Institute's Carcinogenesis Program.[21] Unlike the failure to adduce critical methodology that we criticized in *International Harvester*,[22] EPA's specific enunciation of its underlying analytic principles, derived from its experience in the area, yields meaningful notice and dialogue, enhances the administrative process and furthers reasoned agency decisionmaking.

The animal experiments the Administrator relied on tested heptachlor, its chief metabolite heptachlor epoxide and chlordane. Technical or commercial heptachlor and chlordane both contain the substances tested.[23] Five studies involved mice and one involved rats. Velsicol urges that only the chlordane studies can be relied on to support a finding of carcinogenicity for chlordane, and more broadly, that there was insufficient objective evidence of carcinogenicity in laboratory animals to find a cancer risk to man. The objective evidence Velsicol charges is lacking is evidence that the tumors induced during the feeding studies had properties of invasion (spreading of a tumor into adjacent tissues) and metastasis (spreading of malignant cells into non-adjacent tissues)—characteristics two of their witnesses considered essential definitional elements of "cancer." By contrast, the other pathologists consulted during the suspension proceeding generally believe that cancer can be reliably diagnosed by observation of tissue cells under a microscope (histopathological evidence) without evidence, or very much evidence, of invasion or metastasis. The Administrator concluded, on what we view as respectable scientific authority, that evidence of invasion and metastasis is not essential to the diagnosis of cancer in mice, and also found that metastasis and invasion had been reported in some of the studies where protocols for the study did not preclude such analysis. That a low percentage of metastasis was found in those studies was also explained by the failure to use the more sensitive examination techniques developed since the studies relied on here were carried out.

[21] *See also*, EDF v. EPA, 167 U.S. App. D.C. 71, 78, 510 F.2d 1292, 1299 (1975); Synthetic Organic Chemical Manufacturers Association v. Brennan, 503 F.2d 1155, 1160 (3d Cir. 1974), *cert. denied*, 420 U.S. 973 (1975).

[22] 155 U.S. App. D.C. 411, 439, 478 F.2d 615, 643 (1973).

[23] Technical chlordane was arbitrarily named, and actually is made up of 13-15% alpha-chlordane, 13-15% gamma-chlordane, and 5-8% heptachlor. ALJ Recommended Decision at 7.

In reviewing and evaluating the studies relied on by the Administrator, five EPA witnesses and five Velsicol consultants agreed that animals fed chlordane and animals fed heptachlor/heptachlor epoxide in fact underwent cellular changes indicating malignancy. Dr. Reuber reevaluated the FDA C3H Mouse Study of 1965 and found "a statistically significant increase in carcinomas" in the mice treated with heptachlor/heptachlor epoxide. The ALJ concluded that no substantial refutation of his results was made.[24] The 1959 Kettering CFN Rat Study tested heptachlor epoxide; five pathologists found that the original evaluation had underdiagnosed liver cancer, the biological significance of which was found by Judge Perlman to be "especially significant because of the rarity of this finding."[25] Histological review of the IRDC CD-1 Mouse Study, using a hardy non-inbred strain of mice with low incidence of spontaneous tumors, resulted in the finding of "a highly statistically significant incidence of hepatocellular carcinomas" for those mice fed heptachlor/heptachlor epoxide,[26] and basically the same finding for mice

[24] ALJ Recommended Decision at 78, 82.

[25] ALJ Recommended Decision at 82.

[26] ALJ Recommended Decision at 80.

fed chlordane.[27] After considering design problems of control group and dosages, the Administrator also relied on the preliminary results of National Cancer Institute B6C3 F1 Mouse Studies of Heptachlor and Chlordane, showing a highly statistically significant increase in carcinomas in a strain of mice with a low spontaneous incidence of tumors.[28] The Administrator has adequately explained his reliance on these test results which show significant carcinoma development in treated animals. None of the tests yielded negative results; chlordane was shown to be independently carcinogenic, as well as to contain a carcinogenic component (heptachlor/heptachlor epoxide). We think it plain that the foregoing establishes substantial evidence supporting the Administrator's result, and that Velsicol cannot be said to have met its burden of overcoming EPA's prima facie case by showing that chlordane and heptachlor are not carcinogenic in laboratory animals.

2. *Extrapolation of Animal Data to Man*

Human epidemeology studies so far attempted on chlordane and heptachlor gave no basis for concluding that the two pesticides are safe with respect to the issue of cancer.[29] To conclude that they pose a carcinogenic risk to humans on the basis of such a finding of risk to laboratory animals, the Administrator must show a causal connection between the uses of the pesticides challenged and resultant exposure of humans to those pesticides. He made that link by showing that widespread residues of heptachlor and chlordane are present in the human diet and in human tissues. Their widespread occurrence in the environment[30] and ac-

[27] ALJ Recommended Decision at 80.

[28] Administrator's Opinion at 23.

[29] ALJ Recommended Decision at 86, n.25; Administrator's Opinion at 18-19.

[30] EPA Ex. 20 (Carey); EPA Ex. 24A-C (Seba); VCC Ex. 6, Tr. 3268 (Fink); VCC Ex. 7 (Feltz).

cumulation in the food chain[31] is explained by their chemical properties of persistence, mobility and high solubility in lipids (the fats contained in all organic substances). Residues of chlordane and heptachlor remain in soils and in air and acquatic ecosystems for long periods of time.[32] They are readily transported by means of vaporization, aerial drift, and runoff of eroding soil particles.[33] The residues have been consistently found in meat, fish, poultry and dairy products monitored in the FDA Market Basket Survey and are also frequent in components of animal feeds. This evidence supports a finding that a major route of human exposure is ingestion of contaminated foodstuffs.[34] EPA's National Human Monitoring Survey data shows that heptachlor epoxide and oxychlordane, the principal metabolites of heptachlor and chlordane respectively, are present in the adipose tissue of over 90% of the U.S. population.[35]

The population's exposure to these pesticides, in large part involuntary, can be divided into agricultural and non-agricultural related routes. Seven million pounds of hepta-

[31] ALJ at 9-12, 18-19; EPA Exs. 16, 16I, 16L (Cummings); EPA Ex. 17 (Munsen); EPA Ex. 23 (Sanborn); VCC Ex. 5 (Macek).

[32] USDA Exs. 5, 5A-5E (Nash); EPA Exs. 21, (Taylor); EPA 17 (Munsen); 23B (Sanborn); EPA Ex. 24 (Seba).

[33] VCC Ex. 13A at 1628-1675; USDA Ex. 5F, Tr. 5978 (Nash); EPA Ex. 17 (Munsen); EPA Exs. 21, 21C-F (Taylor); EPA Ex. 24 (Seba); VCC Ex. 7 (Feltz), 4106-13 (Polen); 3292-94, 3310 (Feltz).

[34] ALJ Recommended Decision at 18.

[35] ALJ at 9-11; EPA Ex. 18 (Kutz). Between 1970 and 1974, heptachlor epoxide residues averaging .08-.09ppm were found in 94.8%, 96.2%, 90.3%, 97.7% and 96.3% respectively of the human fat samples tested. Between 1971 and 1974, oxychlordane residues averaging .10-.12 ppm were found in 93.3%, 92.3%, 98.3% and 98.6% respectively, of the samples analyzed.

chlor and chlordane were used as corn soil insecticide in 1975, producing residues which persist in the soil for several years after application. These residues are taken up by such food, feed, and forage crops as soybeans, barley, oats, and hays typically rotated with corn.[36] By volatilization the pesticides contaminate corn and other plant leaves.[37] And root crops like potatoes, carrots and beets directly absorb the pesticides from the soil.[38] Other sources of agricultural-related residues include exposure to contaminated dust particles and agricultural runoff containing eroded soil particles.

Velsicol urges that the dietary exposure resulting from agricultural uses of the pesticides is insignificant, and that current exposure is well below "safe" dose levels as calculated by the Mantel-Bryan formula, or by the World Health Organization's Acceptable Daily Intake figures. Mantel himself criticized the use of the formula for a persistent pesticide, and the Administrator rejected the concept of a "safe" dose level defined by mathematical modeling because of "the incomplete assumptions made by the registrant's witnesses about the sources of human exposure in the environment, the natural variation in human susceptability to cancer, the lack of any evidence relating the level of human susceptability to cancer from heptachlor and chlordane as opposed to that of the mouse, and the absence of precise knowledge as to the minimum exposure to a carcinogen necessary to cause cancer."[39] That explanation is within the reasonable bounds of the agency's expertise in evaluating evidence. And it is confirmed by the common sense recognition that reliance on average "safe" dietary levels fail to protect people with dietary patterns based on high proportional consumption of residue-contaminated foods (*e.g.*, children who ingest greater quantities of milk than the general population).[40]

[36] EPA Exs. 21, 21B (Taylor); EPA Exs. 16C, 16E, 16G (Cummings); USDA Exs. 5, 5H, 5I, 5K, 5L (Nash).

[37] USDA Ex. 5K (Nash); EPA Exs. 21, 21C-21F (Taylor); EPA Ex. 24 (Seba).

[38] EPA Exs. 16, 16B, 16C (Cummings); USDA Ex. 5K (Nash).

[39] Administrator's Opinion at 29; ALJ Recommended Decision at 86; EPA Ex. 43 (Mantel); EPA Exs. 45, 45A at 16-17 (Schneiderman); Tr. 4948-53, 4967 (cross-examination of Carlborg); Tr. 8474-8482, 8525 (Mantel).

There are several non-agricultural uses which involve a large volume of heptachlor and chlordane as well as significant human exposures. For example, the record shows that approximately six million pounds of chlordane are used annually on home lawns and gardens. The Administrator found that these uses involve high risks of human intake "due to the many avenues which exist for direct exposure, through improper handling and misuse, inhalation, and absorption through the skin from direct contact."[41] Velsicol asserts that the mice studies showing carcinogenic effects after ingestion of chlordane do not warrant an inference about the carcinogenic effects of inhaling it or absorbing it through the skin, and that consequently nonagricultural routes of exposure cannot be considered to present a cancer risk. They rely on *Reserve Mining Co* v. *EPA*, 514 F.2d 495 (8th Cir. 1975) (en banc). That reliance is misplaced. In that case, the court was concerned with the propriety of the district court's granting the immediate relief of shutting down a plant discharging asbestos fibers into the City of Duluth's drinking water source. It instead ordered cessation of dumping within a "reasonable time" pursuant to the unstructured equitable discretion given the court under the Federal Water Pollution Control Act, even though it had concluded that continued discharge posed a hazard to health. By contrast, the

[40] EPA Ex. 19 (Kutz); VCC Ex. 4A at 22, Tr. 3124, 7366-67 (Duggan).

[41] Administrator's Opinion at 47.

FIFRA statutory scheme mandates explicit relief—the suspension of registration—when an unreasonable risk to health is made out. We have previously held that it is not necessary to have evidence on a specific use to be able to conclude that the use of a pesticide in general is hazardous. Once the initial showing of hazard is made for one mode of exposure in a suspension proceeding, and the pesticide is shown to be present in human tissues, the burden shifts to the registrant to rebut the inference that other modes of exposure may also pose a carcinogenic hazard for humans.[42] Velsicol has totally failed to meet that burden here. Although it was put on notice in the Notice to Suspend of EPA's intent to rely on direct inhalation and dermal exposure as reasons to suspend household lawn and turf uses of chlordane, it failed to offer even a medical theory as to why the significant inhalation or dermal exposure associated with such uses would *not* pose a carcinogenic threat. In view of the general failure to understand the mechanics of carcinogenicity, the lack of hypothetical explanation may be based on Velsicol's own data that exposure to vapors of chlordane and heptachlor in the work place, leads (as dietary exposure leads) to storage of oxychlordane, heptachlor epoxide, and other components in the fat tissue, and to circulation of these compounds in the blood, with consequent exposure to other organs in the body.[43] Nor did Velsi-

[42] Velsicol asked this court to take judicial notice of the EPA's Interim Procedures & Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21402-05 (May 25, 1976), particularly § 3.5.3 that "[s]ome judgment should be included regarding relevance of the mode of exposure." In view of the no benefit finding from continued use of chlordane and heptachlor in household lawn and turf care, and the pesticides' characteristics of persistence, biomagnification and lipid solubility, that standard does not appear to have been violated here, although the Administrator was not explicit on the point. *Cf.* EDF v. EPA, 167 U.S. App. D.C. at 80, 510 F.2d at 1301.

[43] VCC Ex. 36A. We note that the reliance placed by Velsicol on the Eighth Circuit's distinction between modes of exposure in

col focus on the individual user's intense inhalation exposure associated with lawn and turf uses in its response to the point made in the EPA Staff's exceptions to the ALJ recommended decision, that the evidence showed that an individual using these chemicals for lawn and turf applications is subjected to a marked intensity of inhalation. Instead Velsicol attacked as inconsistent with the minimal amounts of chlordane and heptachlor normally found in ambient air, the EPA Staff's proposed reliance on inhalation as a major route of human exposure for the general population. However, the Administrator did not proceed on this basis. And if Velsicol hypothesized that chlordane residues are safe so long as they reach the tissue only through inhalation (even intense inhalation) it should have presented witnesses expressing that hypothesis. Instead they argue, in general and procedural terms, that the evidence presented by the Administrator was not sufficient to meet his full burden, and this in our view seeks to impose a broader burden on the Administrator than is appropriate in a suspension proceeding.

B. *Benefits*

Velsicol and USDA challenge the Administrator's finding that the benefits derived from the suspended uses of chlordane do not outweigh the harms done. EDF urges that the Administrator's decision to continue some uses was not justified by evidence that the risk of harm was outweighed by benefits from the continued uses.

Reserve Mining fails to take into account as well the very different chemical properties that characterize asbestos as opposed to the properties exhibited by heptachlor/chlordane. Unlike the pesticides at issue here, asbestos fibers are apparently not mobile or lipid soluble, so it was possible that the ingested asbestos—the exposure route where there was less evidence—would pass straight through the digestive tract rather than being retained. There was no comparable hypothesis advanced for the inhalation exposure route questioned here.

1. *Use on Corn*

Heptachlor and chlordane were used on an estimated 3.5% of the total corn acreage in the United States in 1975, largely in an effort to control black cutworm. Cutworms sporadically infest 2 to 8% of total U.S. corn farms, and occur most often in lowland, river bottom areas. Chlordane and heptachlor are used as preplant treatments to insure against possible infestations. The Administrator found, with record support, that no macroeconomic impact will occur as a result of suspending those pesticides. He also found that crop surveillance or "scouting" for infestations during the early weeks of plant growth, together with application of post-emergence baits or sprays where necessary, provide an effective alternative to the more indiscriminate prophylactic use of chlordane and heptachlor. Velsicol urges that this approach is not as effective as the persistent protection provided by chlordane. Especially in the absence of proof of a serious threat to the nation's corn, there is no requirement that a pesticide can be suspended only if alternatives to its use are absolutely equivalent in effectiveness. The Administrator reasonably took into account that a transition period would be necessary to implement post-emergent techniques of control and concluded that the challenged pesticides could continue in use for corn protection until August 1, 1976.[44] This evaluation of alternatives and the time required to implement them is supported by substantial evidence, and we find no basis to disturb the Administrator's balancing of costs and benefits.

[44] EDF argues that it was illegal for the Administrator to delay implementation of his suspension on corn. Such a delay is specifically authorized by the FIFRA, 7 U.S.C. § 136m(b)(2), which provides that "the Administrator may provide a reasonable time for use or other disposal" of a suspended pesticide.

2. *Miscellaneous Agricultural Uses*

The Administrator suspended a number of agricultural uses where the record was insufficient to support any finding that benefits outweigh costs of continued use of heptachlor or chlordane on these crops.[45] Possibly the lack of benefits evidence reflected readily available alternatives, possibly a relative lack of interest in lesser-volume uses. In any event, the registrant's failure to carry its burden of adducing sufficient evidence on benefits in effect leaves the Administrator nothing to weigh in his cost-benefit analysis except the evidence that the use of the challenged pesticides in general is hazardous. That evidence of general hazard is sufficient to support a suspension of uses.

3. *Non-Agricultural Uses Suspended by the Administrator*

Chlordane is a common household, lawn, garden, and ornamental turf insecticide, with over 7.5 million pounds (36% of total use) so employed in 1974. The ALJ and Administrator found on the basis of substantial evidence that the "efficaciousness of the substitutes for control of household and lawn insects is not really at issue"[46] and

[45] Velsicol also urges that the December 24, 1975, Order suspended agricultural registration of chlordane and heptachlor for corn pests alone, and that the Administrator lacked jurisdiction to issue the January 19th order it views as suspending for the first time more than 100 miscellaneous agricultural registrations of the pesticides. We reject that contention. The January 19th order merely clarifies the December 24th order. The Administrator's December 24th decision noted that the ALJ determined that uses of which no benefits evidence was presented should be suspended. We cannot read the December 24th order as contemplating continued use of hazardous pesticides in the absence of any reliable record evidence of benefits to be derived from continued use.

[46] ALJ Recommended Decision at 102, EPA Ex. 26 at 32-34, Ex. 26T, NPCA Ex. 1-5. There is of course no requirement that substitutes for suspended pesticides be absolutely equivalent in effectiveness for a particular use.

that when lack of evidence of substantial benefits from continued use is weighed against the special hazards of exposure presented by the possibilities of inhalation, dermal absorption, and the increased dangers associated with improper handling, suspension of those uses was justified. Similarly, on the basis of evidence in the record, the Administrator could reasonably find that the residual capacity of chlordane was not necessary to control either structural pests or ticks and chiggers, given the existence of effective alternatives to each of those uses.[47]

4. *The Administrator's Refusal to Suspend Certain Uses*

EDF challenges the Administrator's refusal to suspend use of chlordane or heptachlor on strawberries, for seed treatment, pineapples, the white fringed beetle, Florida citrus, white grubs in Michigan, narcissi bulbs, harvester ants, imported fire ant, Japanese beetle quarantine, and black vine weevil quarantine in Michigan. Following the recommendations of the ALJ, the Administrator found that for each use the benefits outweighed the risks for the limited time under consideration, effective alternatives were generally not available, and that the exposure risk arising from the use was minimal. EDF counters that the total exposure resulting from these "minor" uses is in fact significant, and that the Administrator continued these uses whenever a "colorable" case of benefits had been made out.

Once the Administrator has found that a risk inheres in the use of a pesticide, he has an obligation to explain how the benefits of continued use outweigh that risk. We are satisfied that he has met that obligation here, and that substantial evidence supports his decision. We note, however, that we come to this conclusion in the context of a suspension proceeding where perforce the Administrator is

[47] Administrator's Opinion at 36, 48.

engaged in making a "preliminary assessment" of the evidence; a more careful exploration of economic impact and available alternatives would be required to support continued registration in a cancellation proceeding.

C. *Continued Sale and Use of Existing Stocks of Chlordane and Heptachlor for Suspended Uses*

Although we have no doubt that the Administrator has the power under FIFRA to exempt from a suspension order the use of existing stocks (in this case stocks existing as of July 29, 1975), the Administrator acted arbitrarily when he failed to even inquire into the amount of stocks left, and the problem of returning and disposing of them. *Some* evidence must be adduced before an exemption decision is made, and it is the responsibility of the registrant to provide it.[48] It may be that the lapse of time has lessened the current significance of this issue but we are in no position to do other than remand for further consideration.

We affirm the Agency's suspension order of December 24, 1975, as clarified by the order of January 19, 1976, except for the exemption of the sale and use of existing stocks. The record is remanded for further consideration of that issue.

So ordered.

[48] Some evidence on this question has since been made available to this court by Velsicol, but we do not consider ourselves in a position to evaluate it.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 75-2259

ENVIRONMENTAL DEFENSE FUND, INC., *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY AND
RUSSELL E. TRAIN, ADMINISTRATOR, *Respondents*
VELSICOL CHEMICAL CORPORATION
PINEAPPLE GROWERS ASSOCIATION OF HAWAII, ET AL.,
Intervenor

No. 76-1181

EARL L. BUTZ, SECRETARY OF AGRICULTURE, OF THE
UNITED STATES, *Petitioner*

v.

RUSSELL E. TRAIN, ADMINISTRATOR OF THE
ENVIRONMENTAL PROTECTION AGENCY, *Respondent*
VELSICOL CHEMICAL CORPORATION, *Intervenor*

Supplemental Opinion on Petition for Rehearing

Filed January 6, 1977

Before: LEVENTHAL, ROBINSON and WILKEY, *Circuit Judges*

ORDER

On consideration of the petition of Velsicol Chemical Corporation for rehearing it is

ORDERED by the Court that the aforesaid petition for rehearing is denied.

Supplemental Opinion for the Court filed by *Circuit Judge* LEVENTHAL.

SUPPLEMENTAL OPINION ON
PETITION FOR REHEARING

LEVENTHAL, *Circuit Judge:* Velsicol argues in its petition for rehearing that in upholding the Administrator's allocation of the burden of proof to the registrant this Court misinterpreted § 7c of the Administrative Procedure Act. Velsicol points out that the interpretation adopted by this Court was not advanced by any of the parties and that, in fact, the problem of interpreting the APA—as opposed to section 6(c)(2) of FIFRA—was not briefed or argued in this proceeding.

In light of these contentions, we have reexamined our analysis of the APA and FIFRA. After further study, we are still of the view that the Administrative Procedure Act does not preclude the assignment of the burden of persuasion to the opponent of an order. So far as this case is concerned, however, Velsicol's position is undermined by still another doctrine, that in any event the controlling statute is FIFRA. We hold that in light of the legislative history of FIFRA, and the numerous cases holding that its 1964 amendment was specifically intended to shift the burden of proof from the Secretary to the registrant, this case is one where the location of the burden of proof is, in the language of the APA, "otherwise provided by statute." 5 U.S.C. § 556(d).

I

As to the APA, our opinion holds that the "burden of proof" it casts upon the "proponent" is the burden of coming forward with proof, and not the ultimate burden of persuasion.

Velsicol claims that the precedents of this Circuit [1] and case law in other circuits [2] establish that under the APA the proponent of an order bears the burden of persuasion.

We have examined the cited cases and find no support for that view. Time does not permit discussion of each case. We shall refer to a few as illustrations.

Velsicol calls attention to *National Airlines, Inc.* v. *Civil Aeronautics Board,* 112 U.S.App.D.C. 119, 300 F.2d 711 (D.C. Cir. 1962). There we affirmed an order that held that once a complaining City had demonstrated the inadequacy of existing airline service, the airline bore the burden of proving the economic infeasibility of expanding service. The court explained:

> Petitioner argues that the Administrative Procedure Act, § 7(c), 69 Stat. 241 (1946), 5 U.S.C. A. § 1006(c), which places the burden of proof upon the proponent of an order, prohibits the Board from placing the burden of proving economic infeasibility upon the carriers. We think that once the Board has established

[1] Velsicol cites National Airlines, Inc. v. C.A.B., 112 U.S. App. D.C. 119, 123 n. 12, 300 F.2d 711, 715 n. 12 (1962); Schramm v. Physical Therapists Examining Board, 129 U.S. App. D.C. 347, 394 F.2d 972 (1967), *cert. denied,* 390 U.S. 987 (1968), *aff'g* 219 A.2d 846 (D.C.C.A. 19-6); Philadelphia Co. v. S.E.C., 84 U.S. App. D.C. 73, 175 F.2d 808 (1948), vacated as moot, 337 U.S. 901 (1949).

[2] Velsicol cited United States v. Springer, 491 F.2d 239, 242 (9th Cir. 1974); Day v. National Trans. Safety Board, 414 F.2d 950 (5th Cir. 1969); N.L.R.B. v. Atlanta Coca-Cola Bottling Co., 293 F.2d 300 (5th Cir. 1961); Kerner v. Fleming, 283 F.2d 916, 921-22 (2d Cir. 1960); Kirby v. Shaw, 358 F.2d 446, 449 (9th Cir. 1960).

> that existing service is inadequate to meet the needs of a community, it has discharged its burden of proof. Economic infeasibility is more like an affirmative defense than an element of the Board's case. Accordingly we think that the Board properly placed the burden of producing evidence of economic infeasibility upon petitioner.

112 U.S.App.D.C. at 123 n. 12, 300 F.2d at 715 n. 12. Far from indicating that the APA governs allocation of the burden of persuasion, this passage indicates that it was the burden of producing evidence that was the central concern of the APA.[3]

Our examination of the precedents cited from other Circuits has similarly failed to disclose a case holding that under the APA the proponent of an order bears the burden of persuasion. Most of the cases cited by Velsicol appear to think of "burden of proof" as the burden of producing evidence. *See, e.g., N.L.R.B.* v. *Atlanta Coca-Cola Bottling Co.,* 293 F.2d 300 (5th Cir.) rehearing denied, 296 F.2d 896 (1961); *United States* v. *Springer,* 491 F.2d 239, 242 (9th Cir.) *cert. denied,* 419 U.S. 834 (1974); *Kirby* v. *Shaw,* 358 F.2d 446 (9th Cir. 1966).[4] The one case cited by Velsicol

[3] The other decisions of this Circuit do not detract from this conclusion. In *Philadelphia Co.* v. *SEC, supra* at note 1, the SEC had undertaken action with respect to the company by amending its Rules. It had not apprised the company of the facts upon which its action was based, "and it failed to introduce or receive evidence, to hear witnesses, to permit cross-examination, and to make a proper transcript of record." 175 F.2d at 818. It was in this context—in the total absence of an adjudicatory hearing—that we held that the Commission had "erroneously failed to assume the burden of proof in respect to the propriety of its proposed action." *Id.* In *Schramm* v. *Physical Therapists Board, supra,* at note 1, we upheld a decision of the D.C. Court of Appeals which found that an applicant had failed to meet her statutory duty of "present[ing] evidence" of her qualifications. 219 A.2d at 847.

[4] In *Atlanta Coca-Cola,* for example, the court was concerned

that is explicitly concerned with the "burden of persuasion" is *Kerner* v. *Flemming,* 283 F.2d 916, 921-22 (2d Cir. 1960). Judge Friendly assumed arguendo ("We may agree") that under the APA and the Social Security Act "an applicant for a disability pension has the ultimate burden of persuasion." This did not govern the result, for the court did not affirm the denial of benefits but remanded for the taking of further evidence.[5]

As for *American Trucking Associations* v. *United States,* 344 U.S. 298, 319 (1953), in holding that § 7(c) of the APA did not apply to the proceedings in suit, the Court merely put it as an assumption for sake of discussion:

> But even assuming that the Commission was a statutory "proponent" of the regulation and that it did not actively introduce the requisite degree of proof in support of its position, we think it plain that the requirement is inapplicable to the instant proceedings.

Our further research outside our circuit has yielded *Old Ben Coal Corp.* v. *Interior Bd. of Mine Operations Appeals,* 523 F.2d 25 (7th Cir. 1975), involving a situation and a ruling like ours. Appellants challenged a regulation that placed on the mine owner the burden of proving by a preponderance of the evidence the invalidity of the imminent danger withdrawal orders issued against him. The court held that in its view the Government bore the initial burden

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with the General Counsel's failure to produce evidence of discriminatory intent as to each of the individual employees, rather than with the placement of the burden of persuasion. *See, e.g.,* 292 F.2d at 309 ("This is not a case where conflicting inferences of equal weight may be drawn from the record.")

[5] That the court did not intend this passage to state doctrine with respect to the allocation of the burdens of proof or persuasion is indicated by its appended footnote 8, which stated "Congress has often spoken more clearly when it has desired to fix a burden of proof. [citing statutes]."

of going forward with the evidence, but that once it had presented a *prima facie* case, the mine owner would be required to bear the "ultimate burden of proof." 523 F.2d at 30.[6] The Court explained:

> In practice . . . the burden of proof is split, with the Government bearing the burden of going forward, and the mine operator bearing the ultimate burden of persuasion. We think that this accords with the intent of Congress as expressed in the . . . Committee comment on section 7(c) of the Administrative Procedure Act (now codified as 5 U.S.C. § 556(d)) [citations omitted]

The legislative history of § 7(c) of the APA confirms the Seventh Circuit's interpretation. We set out the whole of the pertinent paragraph of the Senate Committee Report:[7]

> That the proponent of a rule or order has the burden of proof means not only that the party initiating the proceeding has the general burden of coming forward with a prima facie case but that other parties, who are proponents of some different result, also for that purpose have a burden to maintain. Similarly the requirement that no sanction be imposed or rule or order be issued except upon evidence of the kind specified means that the proponents of a denial of relief must sustain such denial by that kind of evidence. For example, credible and credited evidence submitted by the applicant for a license may not be ignored except upon the requisite kind and quality of contrary evidence. No agency is authorized to stand mute and arbitrarily disbelieve credible evidence. Except as applicants for a license or other privilege may be required to come forward with a prime facie showing, no agency

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[6] Judge Pell dissented.

[7] S. Rep. No. 752, 79th Cong., 1st Sess. 22 (1945), *reprinted* in S. Doc. 248 at 208.

> is entitled to presume that the conduct of any person or status of any enterprise is unlawful or improper.

Plainly, this is all concerned with the proponents being required to show the burden of producing evidence.

The House Report[8] fully confirms this view. It contains the language quoted above from the Senate Report, and summarizes its effect:

> In other words, *this section means that every proponent of a rule or order or the denial thereof has the burden of coming forward* with sufficient evidence therefor; and in determining applications for licenses or other relief any fact, conduct, or status so shown by credible and credited evidence must be accepted as true except as the contrary has been shown or such evidence has been rebutted or impeached by duly credited evidence or by facts officially noticed and stated. (Emphasis added).

Velsicol points out that an earlier version of S.7 had provided:

> The proponent of a rule or order shall have the burden of proceeding except as statutes otherwise provide." (S.Doc 248, 79th Cong., 2d Sess. 11, 158, 300 (1945)).

A Senate Judiciary Print comparing the earlier and later versions of the bill stated:

> The provision relating to burden of proof is the standard rule. Senate Doc. 248 at page 31.

Velsicol contends that this change in language was intended to make clear that the proponent of an order would also bear the burden of persuasion.

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[8] H.R. Rep. 1980, 79th Cong., 2d Sess. 34 (1946), *reprinted in* S. Doc. 248 at 270.

This argument is more revealing of the ingenuity of counsel than of the intent of Congress. If the language of the bill had been deliberately changed to govern placement of the burden of persuasion, the Committee reports accompanying the bill would have made that point.

Lastly, we note that our interpretation of § 7(c) is supported by the *Attorney General's Manual on the Administrative Procedure Act,* published in 1947 "primarily as a guide to the agencies in adjusting their procedures to the requirements of the Act." (Intro. by Att. Gen. Tom Clark, page 6). The *Manual* does not mention the change in language as bearing on location of the burden of persuasion. On the contrary, it states (at p. 75):

> There is some indication that the term "burden of proof" was not employed in any strict sense, but rather as synonymous with the "burden of going forward". In either case, it is clear from the introductory clause that this general statement was not intended to repeal specific provisions of other statutes which, as by establishing presumptions alter what would otherwise be the "burden of proof" or the "burden of going forward".

II

Section 7(c) of the APA provides that the proponent of a rule or order shall have the burden of proof "[e]xcept as otherwise provided by statute." Because we held in our panel opinion that § 7(c) was not intended to govern the allocation of the burden of persuasion, we found it unnecessary to decide whether suspension hearings held under FIFRA might not qualify as a situation where the location of the burden of proof was "otherwise provided by statute." Velsicol's challenge has led us to focus again on the problem. We have examined the relationship between FIFRA and the APA and conclude that suspension hearings do indeed fall within the exceptions to § 7(c).

This court has repeatedly held that the 1964 amendments to FIFRA were specifically intended to shift the burden of proof from the Secretary (now the Administrator) to the registrant. *EDF* v. *Ruckelshaus,* 142 U.S.App.D.C. 74, 93, 439 F.2d 584, 593 (D.C. Cir. 1971); *EDF* v. *EPA* [Aldrin and Dieldrin], 150 U.S.App.D.C. 348, 465 F.2d 528, 532 (D.C. Cir. 1972); *EDF* v. *EPA* [Shell Chemical Co.], 167 U.S.App.D.C. 71, 76, 510 F.2d 1292, 1297 (1975). In *EDF* v. *Ruckelshaus, supra,* the court explained:

> Prior to 1964, the FIFRA required the Secretary to register "under protest" any pesticide or other item that failed to meet the statutory requirements. The product remained on the market, and the Secretary reported the violation to the United States Attorney for possible prosecution. In 1964 the statute was amended to eliminate the system of protest registration, and substitute the present administrative mechanism for cancelling registrations. The stated purpose of the amendment was to protect the public by removing from the market any product whose safety or effectiveness was doubted by the Secretary.

The House Committee Report accompaninying the bill specifically stated:

> The principal effect of registration under protest is to shift the burden of proof from the registrant to the Government. If the product is not registered, the penalty or seizure provisions can be applied on that ground. If it is registered under protest, the Government has the burden of proving that the product does not comply with the act.
>
> Thus, at present, the Secretary can be required to register a product even though he is convinced that it is ineffective and dangerous to human life. He can proceed against it in such case only after it has moved in interstate commerce, and he then has the burden of proving that it violates the law. The bill would correct this situation and afford greater protection to the public by repealing the authority for registration under protest. In its place the bill provides that applicants dissatisfied with the Secretary's action in refusing or canceling registration may have recourse to advisory committee proceedings, public hearings, and eventually judicial review. Thus the bill affords adequate protection to the public, and protects applicants for registration from arbitrary or ill-advised action by the Department.

H.R. Rep. No. 1125, 88th Cong., 1st Sess. 2 (1964). Thus, we found that "[t]he legislative history supports the conclusion that Congress intended any substantial question of safety to trigger the issuance of cancellation notices, shifting to the manufacturer the burden of proving the safety of his product." 142 U.S.App.D.C. at 83, 439 F.2d at 593.[9]

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[9] We quoted in a footnote from additional legislative history: 34. *See* 110 Cong. Rec. 2948-49 (1964) (remarks of Congresswoman Sullivan):

> I am strongly in favor of the legislation now before you to require industry, rather than the Federal Government, to shoulder the burden of proof in connection with the marketing of pesticides which may be unsafe for use as intended.
>
> • • • •
>
> The burden of proof should not rest on the Government, because great damage can be done during the period the Government is developing the data necessary to remove a product which should not be marketed.

See also H.R.Rep. No. 1125, *supra;* S.Rep. No. 573, 88th Cong., 2d Sess. (1964). Our construction of the FIFRA also finds strong support in a 1969 report of the House Committee on Government Operations, reviewing the administration of the statute. The Committee strongly criticized the administrators for failing to take "prompt or effective cancellation action in cases where it had reason to believe a registered product might be ineffective or potentially hazardous. • • • A mistaken belief

Subsequent decisions reaffirmed this interpretation. In the 1972 *EDF* case, we said (150 U.S.App.D.C. at 352, 465 F.2d at 532):

> The burden of establishing the safety of a product requisite for compliance with the labeling requirements, remains at all times on the applicant and registrant.

In the 1975 *EDF* case, 510 F.2d at 1297, we reiterated this principle in the context of a challenge to a suspension order. Other circuits have similarly concluded that the registrant bears the burden of proof. *E.g., Dow Chemical Corp.* v. *Ruckelshaus,* 477 F.2d 1317, 1324 (8th Cir. 1973); *Southern National Mfg. Co.* v. *EPA,* 470 F.2d 194, 196-97 (8th Cir. 1973); *Continental Chemiste Corp.* v. *Ruckelshaus,* 461 F.2d 331, 335 (7th Cir. 1972); *Stearns Electric Paste Corp.* v. *EPA,* 461 F.2d 293, 303 (7th Cir. 1972).

Velsicol argues that the 1972 Amendments to FIFRA, which provided that a suspension hearing "shall be held in accordance with the provisions of subchapter II of Chapter 5 of Title 5", operated to shift the burden of proof to the agency. *See FIFRA* §6(c)(2), 7 U.S.C §136d(c)(2) (Supp. V 1975). In light of the clarity with which Congress originally undertook to fix the burden of proof (persuasion) on the registrant, and the firmness of the courts' interpretation of the 1964 amendment,[10] we cannot believe

that positive evidence of hazard—rather than simply a lack of adequate assurance of safety—is necessary to support a cancellation action appears to have been a factor in [the] failure to initiate such action in cases where it was obviously justified." H.R.Rep. No. 91-637, 91st Cong., 1st Sess. 15-16 (1969).

[10] Significantly, our decisions had made clear that the registrant bore the burden of proof in suspension hearings even *before* the 1972 Amendments had been enacted. Our 1971 decision in *EDF* v. *Ruchelshaus* noted:

> Because the statute places on the manufacturer the burden of proving the continued safety of his products, see note 34 *infra*, an administrative order of suspension is entitled to greater judicial deference than an order denying suspension.

142 U.S. App. D.C. at 92 n. 22, 439 F.2d at 592 n. 22.

Our statement in EDF v. EPA, 150 U.S. App. D.C. at 352, 465 F.2d at 532, that the burden of proof was "at all times on the applicant and registrant" came 6 months before the enactment of the amendments to FIFRA. The decision of the Seventh Circuit that the registrant bore the burden of proof in suspension proceedings similarly preceded the passage of the Act by 6 months. *See* Stearns Electric Paste Co. v. EPA, 461 F.2d 293 (7th Cir. 1972).

that the general incorporation of APA standards 1972 was intended to shift the burden of proof away from the registrant *sub silentio.*[11] As the ALJ pointed out, "It would be strange indeed, that the 1972 amendment to the act would change the cornerstone of the statute without mention." ALJ Recommended Decision at 73, n. 12. This conclusion would be sound even if the APA, by itself, indisputably put the burden of persuasion on the proponent of suspension. It is strengthened by our conclusion (Part I) that the APA does not have that consequence.

Lastly, we do not discern in the statute an allocation of burden of proof that is different for suspension hearings than for registration or cancellation proceedings. While the suspension proceeding is in progress, the public is subject to the same risks of injury that are present in the cancellation context, the very risks which caused Congress to shift the burden of proof to the registrant in the original registration. Information relevant to the safety issues is—or should be—in the possession of the manufacturer. *Cf. Commonwealth of Puerto Rico* v. *Federal Maritime Comm'n,* 152 U.S.App.D.C. 28, 468 F.2d 872 (D.C. Cir. 1972.) We agree with Judge, now Justice, Stevens that:

[11] Velsicol has not cited nor have we found any statements in the legislative history suggesting that the incorporation of APA standards for suspension hearings was intended to shift the burden of proof.

"If a presumption of proper use at the end of a 5-year period does not shift the burden of proof in the [re-registration situation], we think there is even less reason to shift the burden in the middle of a 5-year term if the Administrator should then become aware of previously unknown risks associated with the use of a product." *Stearns Electric Paste Co.* v. *EPA, supra,* 461 F.2d at 305 n. 38 (7th Cir. 1972). To place the burden of proof on the agency in suspension hearings would not be a reasonable construction of FIFRA.

Our view that this case is one in which the allocation of the burden of proof is controlled by the scheme of FIFRA rather than by the APA is firmly supported by, and interrelated with, the doctrine set forth in *Commonwealth of Puerto Rico* v. *Federal Maritime Comm'n, supra,* that the general rule imposing the burden of proof on the proponent of an order is "subject to reasonable construction and limitation." 152 U.S.App.D.C. at 37, 468 F.2d at 881. The governing statute in that case provided that the burden of proof was to be borne by the carrier in a proceeding in which the proposed rates had been suspended, but did not explicitly provide for the case where the Commission permitted the rates to go into effect. We held that even in the absence of explicit statutory guidance, the burden of proof was to be borne not by the shipper proposing a termination of the existing rate, but by the carrier defending that rate and the increases it wrought. In support of this conclusion we noted the general regulatory pattern and the fact that the carriers were the parties "naturally possessed of pertinent evidence." Both of those considerations are relevant with respect to the burden of proof in FIFRA suspension hearings.

• • • •

In summary, we find that in a suspension hearing conducted under FIFRA § 6(c)(2), the burden of persuasion rests ultimately on the registrant. In its 1964 amendment to

the Act, Congress made clear that the public was not to bear the risk of uncertainty concerning the safety of a covered poison. In the absence of an equally explicit countermanding direction from Congress, we will not force the public to assume it.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT
SEPTEMBER TERM, 1976

No. 75-2259

ENVIRONMENTAL DEFENSE FUND, INC., *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, and RUSSELL E. TRAIN, Administrator, *Respondents*

VELSICOL CHEMICAL CORPORATION
PINEAPPLE GROWERS ASSOCIATION OF HAWAII, ET AL., *Intervenors*

No. 76-1181

EARL L. BUTZ, Secretary of Agriculture of the United States, *Petitioner*

v.

RUSSELL E. TRAIN, Administrator of the Environmental Protection Agency, *Respondent*

VELSICOL CHEMICAL CORPORATION, *Intervenor*

No. 76-1245

VELSICOL CHEMICAL CORPORATION, *Petitioner*

v.

ENVIRONMENTAL PROTECTION AGENCY, RUSSELL E. TRAIN, Administrator, *Respondent*

No. 76-1247

VELSICOL CHEMICAL CORPORATION, *Petitioner*

v.

RUSSELL E. TRAIN, Administrator, Environmental Protection Agency, *Respondent*

PETITIONS FOR REVIEW OF AN ORDER OF THE ENVIRONMENTAL PROTECTION AGENCY

Before: LEVENTHAL, ROBINSON and WILKEY, *Circuit Judges*

Judgment

(filed November 10, 1976)

These causes came on to be heard on petitions for review of an order of the Environmental Protection Agency and were argued by counsel. On consideration of the foregoing, it is

ORDERED AND ADJUDGED by this Court that the Agency's suspension order of December 24, 1975, as clarified by the order of January 19, 1976, is affirmed, except for the exemption of the sale and use of existing stocks. The record is remanded for further consideration of that issue, in accordance with the opinion of this Court filed herein this date.

Per Curiam
For the Court
/s/ GEORGE A. FISHER
George A. Fisher, Clerk

Date: November 10, 1976
Opinion for the Court filed by Circuit Judge Leventhal.

APPENDIX D

ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

FIFRA Docket No. 384

Recommended Decision

In re

VELSICOL CHEMICAL CORPORATION ET AL., *Registrants*

PRELIMINARY STATEMENT

This is a proceeding under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*, 1973 Supp.). Pursuant to section 6(c) of the act (7 U.S.C. 136d(c)), the Administrator, on July 29, 1975, issued a notice of intention "to suspend the registrations and prohibit the production for use of all pesticides containing heptachlor or chlordane other than those registrations exempted from the heptachlor/chlordane cancellation order" (See 40 F.R. 34456).[1] The notice of suspension also contained detailed findings pertaining to the question of "imminent hazard" as required by the act.[2] On August 6, 1975,

[1] As explained in the July 29, 1975 notice, a final order of suspension in this proceeding would not include the suspension of registrations pending the completion of cancellation proceedings for use of heptachlor or chlordane in subsurface ground insertion for termite control and the dipping of roots and tops of nonfood plants. See 39 F.R. 41298 as clarified (40 F.R. 30522). Also, the July 29, 1975 notice of suspension permitted, pursuant to section 15(b)(2) of the act (7 U.S.C. 136m(b)(2)) "continued use of those existing stocks of EPA registered pesticides containing heptachlor or chlordane which have been formulated as of the date of this notice."

[2] Section 6(c)(1) of the act provides that "If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, he may, by order, suspend the registration of the pesticide immediately." The term "imminent hazard" is defined to mean, in part, "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment . . ." (7 U.S.C. 136(l)). "Unreasonable adverse effects on the environment" is defined in the act to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of any use of any pesticide." (7 U.S.C. 136(bb)).

a document entitled "Clarification of Evidence Which May Be Introduced in the Hearing On Suspension of Registrations of Pesticides Containing Heptachlor or Chlordane" was issued (See 40 F.R. 34455).

Velsicol Chemical Corporation, the sole manufacturer of the pesticides involved, filed timely objections to the notice of intention to suspend and prior and subsequent thereto many other registrants also filed objections. In addition, the Secretary of Agriculture of the United States, Environmental Defense Fund, Louisiana State Pest Control Association, Mississippi State Pest Control Association, Florida Nurserymen and Growers Association, Inc., New England Pest Control Association, Georgia State Pest Control Association, Long Island Pest Control Association, North Carolina Pest Control Association, Alabama State Pest Control Association, National Pest Control Association, Inc., United Pesticide Formulators and Distributors Association, Tennessee Pest Control Association, Pest Control Operators of California, New Jersey Pest Control Association, Maryland Pest Control Association, the State of Hawaii and the Pineapple Growers Association of Hawaii, were granted leave to intervene herein pursuant to section 164.121(e) of the rules of practice (40 CFR 164.121(e)).

Section 6(c)(1) of the statute further provides that "No order of suspension may be issued unless the Administra-

tor has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide." By order dated November 18, 1974 (39 F.R. 41298), the Administrator stated his notice of intent "to cancel all registered use of heptachlor and chlordane . . . with the exception of the use of heptachlor or chlordane through subsurface ground insertion for termite control and the dipping of roots or tops of nonfood plants." Objections to such notice were filed by Velsicol Chemical Corporation and many additional registrants in 56 separate proceedings which were consolidated for hearing.

Also on November 18, 1974, the Administrator implemented his authority to register and control intrastate pesticide products with regard to intrastate products containing heptachlor and chlordane, except those registered for use in subsurface ground application for termite control or for dipping of roots or tops of nonfood plants. (39 F.R. 41256). Subsequently, 17 additional proceedings instituted, in effect, by the filing of objections and requests for hearing by applicants contesting the denial of applications for registration under the act of pesticide products containing heptachlor or chlordane and intended for shipment in intrastate or interstate commerce (see 40 F.R. 22587) were consolidated in the heptachlor/chlordane cancellation proceedings (*In re Velsicol Chemical Corporation et al.*, FIFRA Dockets No. 336 et al.)

On August 4, 1975, Herbert L. Perlman, Chief Administrative Law Judge, Environmental Protection Agency, was appointed the Presiding Officer in the suspension proceeding. Prehearing conferences were held August 6, 7, and 11, 1975, and the hearing herein commenced August 12, 1975. All the registrants filing objections to the notice of intention to suspend were consolidated into this proceeding pursuant to section 164.121(f) of the rules of practice. The Administrator ordered that the hearing herein take no longer than 40 hearing days unless for good cause shown

and upon recommendation of the presiding officer he extends the hearing for not more than 10 additional hearing days. The hearing lasted 43 hearing days and the hearing closed December 4, 1975. The active participants at the hearing were represented by the following:

Robert L. Ackerly, Charles A. O'Connor III, Joe G. Hollingsworth and John D. Conner, Jr., Attorneys at Law, Washington, D.C. representing Velsicol Chemical Corporation and many intervenors and other registrants,

Robert L. Weinberg, David Povich, John G. Kester, Robert B. Barnett and Kendra Heymann, Attorneys at Law, Washington, D.C., representing Velsicol Chemical Corporation and several other registrants,

Bernard Lorant, Attorney at Law, Highland Park, Illinois, and Neil R. Mitchell, Attorney at Law, Chicago, Illinois, representing Velsicol Chemical Corporation,

Raymond W. Fullerton, Alfred R. Nolting, Margaret M. Breinholt and Margaret Carlson, Office of the General Counsel, United States Department of Agriculture, representing intervenor Secretary of Agriculture of the United States,

Jacqueline M. Warren and William A. Butler, Attorneys at Law, Washington, D.C., representing intervenor Environmental Defense Fund, Inc.,

Clausen Ely, Jr., Attorney at Law, Washington, D.C., representing intervenors the State of Hawaii and the Pineapple Growers Association of Hawaii, and

William E. Reukauf, Jeffrey H. Howard, Frank J. Sizemore, Lee Schroer, Kevin Lee and Thomas O. McGarity, Office of the General Counsel, Environmental Protection Agency, representing respondent Assistant Administrator, Environmental Protection Agency.

Subsequent to the close of hearing the parties filed briefs and I hereby submit my recommended decision within the exceedingly short period of time provided by the rules of practice.

Findings of Fact

1. Velsicol Chemical Corporation is a corporation whose address is 341 East Ohio Street, Chicago, Illinois. Velsicol Chemical Corporation is the sole manufacturer of heptachlor and chlordane. Velsicol Chemical Corporation and over approximately 400 other registrants filed objections and are parties in this proceeding although Velsicol is the only fully active registrant herein.

2. The intervenors in this suspension proceeding are the Secretary of Agriculture of the United States, Environmental Defense Fund, Inc., Louisiana State Pest Control Association, Mississippi State Pest Control Association, Florida Nurserymen and Growers Association, Inc., New England Pest Control Association, Georgia State Pest Control Association, Long Island Pest Control Association, North Carolina Pest Control Association, Alabama State Pest Control Association, National Pest Control Association,, Inc., United Pesticide Formulators and Distributors Association, Tennessee Pest Control Association, Pest Control Operators of California, New Jersey Pest Control Association, Maryland Pest Control Association, the State of Hawaii and the Pineapple Growers Association of Hawaii. The respondent herein is the Assistant Administrator, Environmental Protection Agency.

3. Technical chlordane has been manufactured and sold commercially since about 1947. Technical chlordane is a complicated insecticidal mixture of chlorinated hydrocarbons. Technical chlordane was arbitrarily named by a joint meeting of representatives of the United States Department of Agriculture, the Food and Drug Administration, and the 2 manufacturers at that time. The name was chosen

on the basis of the belief that this material was composed principally of two compounds, alpha and gamma-chlordane ($C_{10}H_6Cl_8$), because these two compounds were initially isolated in pure form from it. At present (and since about 1950), Velsicol Chemical Corporation is the only commercial producer of technical chlordane. To assure consistency of performance and biological potential, technical chlordane has been standardized by Velsicol and, since about 1950, varies only within narrow limits in its composition. The content of each of the chlordane isomers is 13-15 percent and the heptachlor ($C_{10}H_5CL_7$) content is 5-8 percent. The commercial technical product contains no heptachlor epoxide. In addition, technical chlordane contains several isomers of chlordene ($C_{10}H_6Cl_6$), and nonachlor ($C_{10}H_5Cl_9$). Technical chlordane, a viscous liquid, is a mixture of chlorinated hydrocarbons consisting of isomers of chlordane (1,2,4,5,6,7,8,8-octachloro-4,7-methano-3a,4,7,7a-tetra-hydroindane) and closely related compounds in the presence of minute concentrations of stabilizer (propylene oxide) and by-products. About one-half of the composition consists of two major constituents, isomers of chlordane; no other individual component exceeds about one-tenth of the total product. Its structure corresponds to the empirical formula $C_{10}H_6Cl_8$ having a molecular weight of 409.8. Some of the physical and chemical properties of chlordane are as follows:

Appearance: Amber, viscous liquid.

Solubility: Miscible in aliphatic and aromatic solvents; insoluble in water: low solubility in glycols.

Combustability: Will not burn.

Chemical Stability: Stable to 160 degrees Fahrenheit in stainless steel, nickel, passive iron, glass and many other materials. Decomposes at very high temperature. Sensitive to decomposition at elevated temperatures in the presence of iron and iron oxide dust.

Stability to U.V. light: Stable to U.V. light under normal conditions. Some components will isomerize under the influence of high intensity U.V. light in the presence of U.V. sensitizers such as ketones.

Odor: Mildly pungent.

Boiling Point: 118° at 0.66 mmHg.

4. Heptachlor has been manufactured since about 1950. Technical heptachlor is essentially a ternary mixture consisting of heptachlor (73 percent), gamma-chlordane (about 21 percent) and delta-trichloro-chlordene (nonachlor-5 percent); other manufacturing impurities may occasionally be present in concentrations of up to about 2 percent. Heptachlor can be converted to heptachlor epoxide on plants and by the metabolism of animals. Heptachlor is the common name which has been assigned to 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene. It has the empirical formula $C_{10}H_5Cl_7$, corresponding to a molecular weight of 373.5. In pure form, heptachlor is a white crystalline substance having a melting point of 95° to 96°C.

5. Heptachlor epoxide was found in over 90 percent of the human adipose tissues analyzed in the National Human Monitoring Program [3] at levels ranging from trace to 10.62 ppm with the geometric and arithmetic means ranging for the 5 year period from 0.08 ppm to 0.09 ppm and from 0.10 ppm to 0.17 ppm, respectively, with trace values listed as zero. The arithmetic means for each year from and including 1970 are, respectively, 0.17, 0.12, 0.12, 0.12 and 0.10 ppm and the geometric means for each year from and including 1970 are, respectively, 0.09, 0.09, 0.08, 0.09 and 0.08 ppm.

[3] It must be cautioned that 80 percent of the samples in this program are not subjected to confirmation and use of standard EPA methods may lead to the failure to characterize coextractives which could increase reported results. We do not now so conclude, however.

Specifically the percent positive samples, and percent trace samples are as follows:[4]

Year	Percent Positive	Percent Trace[5]
FY 1970	94.76	3.61
FY 1971	96.23	3.47
FY 1972	90.26	2.86
FY 1973	97.71	1.92
FY 1974	96.33	3.45

The maximums for each of the five years shows a progressive decrease from 1970-1974 as follows: 10.62, 1.53, 1.21, 0.84 and 0.77 ppm. The mean residue concentrations of heptachlor epoxide increased with the age of those sampled and the frequency of detecting residues of heptachlor epoxide also increased with age in every year with the exception of the data collected during the fiscal year 1974 survey. There is little difference in the frequency of detection or in residue concentration between males and females and between Caucasians and Negroes.

6. Oxychlordane was found in over 90 percent of the adipose tissues analyzed in the National Human Monitoring Program at levels ranging from trace to 1.87 ppm, with the geometric mean ranging from 0.10 to 0.12 ppm for the 4 year period and the arithmetic mean at 0.15 ppm, with trace values listed as zero. The percent positive samples and percent trace samples are as follows:

[4] The master file of the National Human Monitoring Program or survey, containing samples in addition to the design file reflected above, has similar results.

[5] Percent trace means the percentage of the total number of samples in which residues of the chemical were found but cannot be quantified.

Year	Percent Positive	Percent Trace
FY 1971[6]	93.27	0.95
FY 1972	92.29	2.71
FY 1973	98.35	1.01
FY 1974	98.55	1.22

The concentration of oxychlordane in human adipose tissue increased with age. The variable nature of the residue data when stratified on a racial basis made trend detection difficult, although oxychlordane residues were found in high frequency in tissues taken from both Caucasians and Negroes. Both males and females displayed high frequency of oxychlordane.

7. A total of 57 human breast milk samples taken in fiscal year 1974 from 49 women residing in Arkansas and 8 women residing in Mississippi, upon analysis, showed that quantifiable levels of heptachlor epoxide were found in 35.09 percent of the samples, with arithmetic and geometric means, with trace values listed as zero, of 0.004 and 0.0017 ppm, respectively, and a range of trace to 0.03 ppm. Quantifiable levels of oxychlordane were found in 45.6 percent of all samples and the residue levels thereof ranged from trace to 0.02 ppm with geometric and arithmetic means, with trace values listed as zero, of 0.0054 ppm. One hundred percent of the milk analyzed contained at least trace amounts of both heptachlor epoxide and oxychlordane, that is, a trace of heptachlor epoxide was found in 64.91 percent

[6] The capability to detect oxychlordane residues in human adipose tissue was initially introduced into the multi-residue analytical technique during the fiscal year 1971 survey. The sample size for 1971 oxychlordane analysis is less than for those other chemicals detectable during the entire year and the results of this survey year (FY 1971) should not be construed as representative of national level. The master file has results similar to those set forth above.

of the samples and a trace of oxychlordane was found in 54.39 percent of the samples. A trace represents a positive finding of residue which cannot be quantified. The presence of heptachlor epoxide was not confirmed by analytical techniques although attempts to do so were performed.

8. Heptachlor epoxide crosses the placental barrier and enters the human fetus. A study of residues of various chlorinated hydrocarbons in different tissues from stillborn infants found measurable concentrations of heptachlor epoxide in parts per million (ppm) in adipose tissue (range, 0.07 to 0.51; mean, 0.32), spinal cord (0.13), adrenals (range, 0.46 to 1.00; mean, 0.73), lungs (range, 0.08 to 0.31; mean, 0.17), heart (range, 0.30 to 1.56; mean, 0.80), liver (range, 0.03 to 1.67; mean, 0.68), kidney (range, 0.19 to 1.14; mean, 0.70), and spleen (range, 0.10 to 0.52; mean, 0.35). Heptachlor epoxide was identified in the cord blood of 27 of the 30 newborn infants or normal neonates studied at levels from 0.2 to 4.3 ppb with a mean of 1.1 ppb.

9. The Urban Soils Monitoring Program indicates, in connection with urban and suburban areas, that residues of chlordane were detected in the soils of all 37 cities sampled between fiscal years 1970 and 1974, heptachlor epoxide was detected in 28 cities and heptachlor in 13 cities. For many cities chlordane was detected in approximately 20 to 40 percent of the samples and in several cities heptachlor epoxide residues were present in 10 to 20 percent of the soil samples. The arithmetic and geometric means of residue values and the frequency of positive detections of these chemicals in most of the cities exceed those observed in the surrounding cropland areas. The majority of occurrences of residues of these chemicals are on lawn sites as distinguished from waste sites of the cities sampled.[7] The resi-

[7] The criteria for defining sites as lawn include mowed grass in close proximity to a house, factory or other structure, mowed grass in municipal parks or other town owned or operated land, garden or cultivated areas and a yard that is in obvious proximity

dues are most likely the result of chlordane applications for control of lawn and garden pests, although some may result from chlordane use in structural pest control. The heptachlor epoxide and heptachlor detected probably result from the contamination of technical chlordane with heptachlor. The data from the Urban Monitoring Program indicate that residues of chlordane, heptachlor and heptachlor epoxide are rather widespread in urban areas, indicating the common use of chlordane in and around human dwellings due to their prevalence in samples from sites classified as lawn.

10. A study of the Chester River in Maryland, designed to ascertain the presence of chlorinated hydrocarbons in the physical environment and biota of the Chester River, and with particular attention to chlordane, established that the alpha and gamma isomers of chlordane were present in shellfish, finfish, crabs and sediments of the Chester River. The average chlordane concentrations found (in parts per million net weight—ppm) were oysters .036, clams .014, fish, .074, crabs .014, and bottom sediments .0052 (dry weight). As part of the Chester River Study, laboratory experiments were performed exposing soft-shelled clams and oysters in a flow-through Baywater system. These experiments demonstrated the shellfish readily accumulated chlordane to high levels from very low concentrations in the water. When exposed to a level of about 1 part per trillion in the water, the oysters concentrated the chlordane 160,000 times. Under similar circumstances, the soft-shelled clams concentrated the chlordane 35,000 times. The chlorinated hydrocarbons were transported adsorbed to the suspended particulate fraction in the water. The chlorinated hydrocarbons appeared to be entering the Chester

to a home. Waste areas are vacant lots where grass is apparently uncared for, small wooded lots, brush or overgrown fields, areas such as power lines, gas lines, etc., and exposed soil around construction sites, eroded areas, etc.

River from the Bay rather than coming from sources within the Chester River watershed.

11. The findings in the Chester River Study which suggested that the chlorinated hydrocarbons were entering the River from the Bay led to the Upper Bay Survey (1973 to 1975), a study of the rates, routes, sources, sinks and reservoirs of chlorinated hydrocarbons in the Upper Chesapeake Bay. Residues of alpha and gamma chlordane were found in all of the types of samples analyzed (air, rainwater, storm-sewer water, zooplankton, suspended sediments, bottom sediments, and benthic organisms). The sum of the alpha and gamma isomers of chlordane in the air samples ranged approximately from 0.5 to 2.0 nanograms per cubic meters of air.[8] The chlordane in rainwater ranged from undetectable (less than 1 part per trillion) to 660 parts per trillion. The chlordane levels in the storm-sewer water samples from a Baltimore residential area ranged from undetectable to 97 parts per trillion. The average chlordane levels found in the other sample types were as follows: shellfish .060 ppm (wet weight); zooplankton .10 ppm (wet weight); suspended sediments .17 ppm (dry weight); and bottom sediments .016 ppm (dry weight).

12. Relatively high levels of the chlorinated hydrocarbons (CHC's) PCB, chlordane, and DDTR were found in the samples from the Upper Chesapeake Bay; CHC's in bottom sediments from the Bay were two-to-four times

[8] The following values are reported as technical chlordane in order to be comparable to the Chester River Study values. The chlordane values reported as technical chlordane in the Upper Bay Survey Report are not directly comparable to those reported in the Chester River Study Report due to a difference in the method in comparing the environmental residue peaks to the technical chlordane standard. In order to compare the technical chlordane values from the Upper Bay Survey Report to the chlordane values presented in the Chester River Study Report, the technical chlordane values from the Upper Bay Survey must be divided by a factor of 2.2.

higher than found in the Chester River. The bottom sediments from Baltimore Harbor were found to contain the greatest amount of the CHC contaminants with values as high as 3.7 ppm for PCB, .23 ppm for chlordane, and .19 for DDTR. The average concentrations of PCB, chlordane and DDTR were highest in suspended sediments filtered from the water in Baltimore Harbor, with high individual values of 3.8 ppm for PCB, 1.7 ppm for chlordane, and .30 ppm for DDTR being found. When these data are presented as the amount of CHC present in the watercolumn on suspended sediment, the average PCB and DDTR values show a decreasing trend going down the Bay with the Harbor station not as high (in the case of PCB) or, in the case of DDTR, about the same as the upper stations. The chlordane is higher in the Harbor than elsewhere in the Bay. The highest chlordane value in zooplankton was found in Baltimore Harbor (.57 ppm), but no one station had consistently high values of chlordane. A positive correlation was found between the concentration of suspended sediments in the water and the concentration of CHC's in the watercolumn on suspended sediments. A positive correlation was also found between the zooplankton biomass in the water and the CHC concentration in the watercolumn on zooplankton. Apparently, the CHC's enter the Bay attached to suspended sediments via the Susquehanna River during periods of high river-flow. These suspended sediments appear to function as a reservoir from CHC's in the Upper Bay. The principle movement from this reservoir probably is into bottom sediments which could be considered sinks or traps for sediment-adsorbed chlorinated hydrocarbons. Resuspension probably represented the greatest pathway for movement of sediment adsorbed CHC's from the sink, although re-working of sediments by deposit-feeding organisms is a possible route which needs further study. The amount of chlorinated hydrocarbons passing into the zooplankton community appears limited only by the zooplankton population density rather than by

fluctuations in the reservoir because the amount of CHC present in the zooplankton standing crop never represents more than a small fraction of that present in the suspended sediment reservoir. Another major pathway from the reservoir into the biological system is into the shellfish populations of the Upper Bay. The chlordane levels in the brackish-water clam often approach the .30 ppm FDA alert level for edible shellfish. Baltimore Harbor receives major inputs of chlorinated hydrocarbons from the inflow of Chesapeake Bay water and suspended sediment. Baltimore Harbor receives localized inputs of CHC's but probably does not serve as a major source of CHC's to the Bay although the chlordane level in the suspended sediment reservoir in the Harbor appears "enriched" compared to that in the Bay.

13. The primary monitoring program for pesticide residues in the nation's food supply are conducted by the United States Food and Drug Administration and the United States Department of Agriculture. There are three major programs. The Food and Drug Administration has two of these. One program, described as the surveillance program, examines large numbers of samples of different foods obtained when lots are shipped in interstate commerce. The other, known as the Total Diet Program, examines food prepared to be eaten. As a part of the surveillance program, the U.S. Department of Agriculture analyzes samples of meats and poultry obtained from processing plants throughout the United States. These three programs comprise the National Pesticide Monitoring Program on Foods. The primary objective of the surveillance program on raw agricultural products by the Food and Drug Administration and the surveillance program on raw meats and poultry by the Department of Agriculture is to determine compliance with tolerances. The primary objective of the Total Diet Program is to estimate the dietary intake of pesticide chemicals.

14. Heptachlor-heptachlor epoxide residues appear most frequently in foods of animal origin, that is, dairy products, meat, fish and poultry. Based on the total diet program, the percent incidence of heptachlor-heptachlor epoxide in all food classes has remained relatively unchanged for the 1965-1974 period, but the calculated daily intake in mg/kg body weight has gradually but steadily declined during the same period. The food residue levels of heptachlor, heptachlor epoxide and chlordane are low. Heptachlor-heptachlor epoxide residues represent 0.8 to 2.0 percent of the ADI for 1970-1974. Chlordane residues comprise less than 1/100 of 1 percent of the ADI. However, chlordane findings in the surveillance program, although still low, have increased recently due perhaps to improved analytical techniques but more likely due to the recent increase in the use of chlordane in agriculture.

15. Chlordane is a commonly used insecticide in agriculture, industry, and the home, lawn and garden. About 21 million pounds were used in the United States during 1974. Data provided by Velsicol Chemical Corporation indicate the following approximate breakdown for chlordane use in 1973 and 1974:

	Mil. lb.		Percent	
Use	1973	1974	1973	1974
Corn	1.94	4.32	10.8	20.4
Potatoes	0.98	1.11	5.5	5.2
Other vegetables	0.06	0.07	0.3	0.3
Home lawn and garden	5.77	6.33	32.1	29.9
Turf	1.14	1.25	6.3	5.9
Strawberries	0.15	0.17	0.8	0.8
Tomatoes	0.30	0.33	1.7	1.6
Ornamentals	0.23	0.25	1.3	1.2
PCO	7.41	7.34	41.2	34.7
Total	17.98	21.18	100.0	100.0

The proposed suspension covers about two-thirds of total chlordane use (65.3 percent in 1974), not counting some PCO use which might also be covered.

16. Chlordane is a leading insecticide in the United States, although it accounts for less than six percent of total U.S. insecticide use. It is widely used in the home and garden and industrial/commercial use areas, where in 1972 it ranked number 1 in each use with about 23 and 30 percent of U.S. use in those respective categories as indicated below:

	Amount Used		
	All insecticides	Chlordane	
Use	Mil. lbs.	Mil. lbs.	Percent
Agriculture	218.9	3.0	1.4
Home and garden	21.8	5.0	22.9
Governmental	7.0	0.5	7.1
Industrial/ commercial	21.5	6.5	30.2
Overall	269.2	15.0	5.5

17. According to USDA surveys, crop uses of chlordane account for 70 to 85 percent of agricultural use of chlordane in the United States and protection of corn from attack by soil insects accounts for more than one half of agricultural use. There is no trend shown in the USDA surveys as to changes in percentage breakdown among general types of agricultural uses. However, there appears to be a trend toward increased use of chlordane in agriculture generally, inasmuch as the 1971 use level of nearly 1.9 million pounds was more than three times that for 1964 and 1966, and more recent estimates by Velsicol indicate that approximately 6 million pounds were used in agriculture during 1974. The suspension of aldrin/dieldrin will increase demand for chlordane, along with other substitutes, leading to increased production and use of chlordane beginning in

1975 or 1976. Government agencies use significant amounts of chlordane. Annual use of chlordane has been estimated at 0.5 million pounds for federal, state and municipal agencies.

18. Heptachlor is used in a much smaller volume than chlordane (about 2 million pounds in 1974 compared with 21 million for chlordane) and is used in fewer types of applications. Data provided by Velsicol Chemical Corporation indicate the following approximate breakdown for use in 1973 and 1974:[9]

	Mil lb.		Percent	
Use	1973	1974	1973	1974
Corn	1.13	1.19	57.4	58.0
Seed dressing	0.19	0.27	9.6	13.2
PCO	0.61	0.55	31.0	26.8
Fire ants, misc.	0.032	0.04	1.6	2.0
Total	1.97	2.05	100.0	100.0

About three-fourths of heptachlor is devoted to agricultural use, and that is largely for corn soil treatments. Corn accounted for 91 percent of agricultural heptachlor use in 1971, according to USDA's survey. The remainder was divided among several other crop uses (e.g., alfalfa, other hay and pasture and vegetables). Heptachlor is not used in connection with livestock producton as is chlordane. Agricultural use of heptachlor is largely in the Corn Belt states, with some use in the Lake States and the Northern Plains. Heptachlor, with agricultural use of about 1.2 million pounds in the early 1970's, equals about 0.5 percent of U.S. agricultural use of insecticides (more than 200 million

[9] The "Fire ant, misc." category of use in the above table includes use on pineapple, which is estimated at about 10,000 pounds annually. Velsicol Chemical Corporation also indicates that there may be several thousand pounds of heptachlor used on citrus to replace suspended aldrin use in Florida.

pounds as of 1972). The PCO use estimate for 1974 of more than 550,000 pounds equals less than 3 percent of U.S. industrial/commercial use (approximately 21.5 million lbs. in 1972).

19. Corn is subject to attack by a wide variety of insects including corn rootworms, wireworms, and cutworms for which chlordane/heptachlor has often been recommended in the past. Chlordane and/or heptachlor have registrations under the act for use against these pests and a number of other lesser economic corn pests. Chlordane and heptachlor are not generally recommended for use against rootworms because resistance has developed. These chemicals are generally recommended by entomologists in the states for use against wireworms and cutworms. The States of Illinois and Iowa do not recommend pre-plant treatment of insecticides against the cutworm and do not recommend heptachlor or chlordane for this purpose. Chlordane and heptachlor together are used on about 2.6 million acres of corn in the United States as of 1975 (3.5 percent of total corn acreage). They are used on about 27,000 farms equalling about 3 percent of commercial corn farms in the United States.

20. Chlordane is used on about 1.2 million acres of corn equalling 1.6 percent of U.S. corn acreage and on about 12,000 farms equalling 1.3 percent of U.S. commercial corn farms as of 1975. Heptachlor is used on about 1.4 million acres of corn equalling 1.9 percent of U.S. corn acreage and on about 15,500 farms equalling 1.7 percent of U.S. commercial corn farms. With suspension of aldrin, the use of aldrin declined from 9.6 percent of U.S. commercial corn acreage in 1973/74 (average of 2 years) to 3.3 percent in 1975. Chlordane use increased to some extent (from 1.3 percent to 1.6 percent of U.S. corn acreage in 1975) while heptachlor use increased somewhat more sharply, from 1.2 percent to 1.9 percent of U.S. corn acreage. Aldrin will no longer be available. Total acreage of corn treated with in-

secticides in the United States declined from 27.9 million in 1973/74 (average of 2 years) to 26.2 million in 1975 even though commercial corn acreage in the U.S. increased nearly 3 million acres. This decline in insecticide use may be associated with the aldrin suspension as aldrin use has declined from near 7 million acres in 1973/74 to near 2.5 million acres in 1975. Two-thirds of the corn grown in the United States is not treated with any insecticide including both soil and foliar applications. Most corn farms do not use insecticides of any type in the production of corn (more than 75 percent in 1975).

21. Several organophosphate and carbamate alternatives to chlordane/heptachlor for control of corn soil insects are in widespread use in the United States as of 1975. Alternatives for rootworms and wireworms are used much more frequently than for cutworms. Diazinon, the only recommended pre-emergence alternative for cutworms, is used on only 0.4 percent of corn acreage and rescue baits are used on limited acreage. The leading states in use of chlordane/heptachlor as of 1975 based on percentage of corn acreage treated with these chemicals were: Missouri, 12.1; Illinois, 6.6; Indiana, 6.2; Iowa, 4.2; Ohio, 3.4; and Minnesota, 0.8 percent. Aldrin was used quite heavily in several of the corn states in 1975 (in terms of the percentage of corn acreage treated): Missouri, 17.9 percent; Indiana, 7.9 percent; Ohio, 7.2 percent; Illinois, 5.0 percent; and Iowa, 3.3 percent. Missouri is by far the heaviest user of organochlorines with 30 percent of commercial corn acreage so treated in 1975. The next ranking state was far below (Indiana with 14.1 percent). The number of commercial corn farms in the United States dropped from near 970,000 in 1973/74 to slightly under 900,000 in 1975, even though total corn acreage increased by more than 2 million acres. Farms using insecticides are larger acreage corn farms than nonusers. This is true of organochlorines as well as other insecticides. Corn insecticide expenditures totalled nearly

$105.7 million in 1975, up considerably from $78.7 million in 1973/74. Average expenditure per treatment acre was $4.04 in 1975 compared with $2.82 per acre in 1973/74. Organochlorine treatments are less expensive than organophosphate and carbamate insecticides.

22. Cutworms are the primary corn soil insect pest for which chlordane and heptachlor are recommended to maintain yields. They are seldom recommended for rootworms. For wireworms many alternatives are recommended. Cutworm infestations in corn are highly variable from year to year. Since 1969 the number of farms reporting cutworms as a major problem has varied from 19,000 to 71,000 in the United States with an overall average of about 53,000. This equals about 2 to 8 percent of U.S. corn farms. The percentage of these farms treating for cutworms during that period ranged from 52 to 71 percent with an overall average of 61 percent. The number of farms treating during 1969 to 1975 averaged about 32,000 and ranged from 13,000 to 48,000. The extreme variability in cutworm infestations frustrates attempts to project economic thresholds for treatment. It is extremely difficult to determine in the spring whether pre-plant treatment would be justified except in high risk fields which have a history of cutworm problems. Rescue bait and spray treatments must be depended upon when there has been no pre-plant treatment or pre-plant treatment has failed in the face of an outbreak. The use of rescue bait and spray treatment requires scouting techniques during the critical time when corn is subject to cutworm damage after emergence from the soil. Scouting is useful even with pre-plant treatment because such treatments at times fail. Rescue treatments for cutworms such as sevin (carbaryl) and dylox (trichlorfon) are in the same cost range as chlordane/heptachlor. These rescue treatments can be less expensive than broadcast aldrin or chlordane/heptachlor treatment. They are not applied unless needed, which lowers costs to the farmer. However, equipment costs may be a factor. Scouting can, in many

cases, be accomplished in connection with other field operations, such as cultivation and routine observation of growing crops. Trained scouts working under a pest management project in Illinois in 1974 cost $0.55 per scouted acre for the season plus an additional $0.44 for computer and other support, bringing total costs to $0.99 per acre.

23. The existence and responsibilities of the Plant Protection and Quarantine Programs (PPQ) of the United States Department of Agriculture are provided for by congressional acts and by delegations made by the Secretary of Agriculture. The Plant Protection and Quarantine Programs operate under the following acts: (1) The Plant Quarantine Act, (2) The Federal Plant Pest Act, (3) Organic Act of September 21, 1944, (4) Mexican Border Act, (5) Terminal Inspection Act, (6) Mexican Pink Bollworm Act, (7) Incipient or Emergency Control of Pests, (8) The Golden Nematode Act, and (9) Cooperation with States Act. The acts provide the Secretary of Agriculture with authority to: (1) establish restrictive and prohibitory quarantines and regulations against imports likely to be the means of introducing plant pests not known to be present or widely distributed in the United States; (2) establish quarantines and regulations to carry out cooperative Federal-State-Mexican programs for suppression, control, or eradication measures against designated plant pests which become established in the United States or Mexico; and (3) provide export certification of domestic plants and plant products when requested by interested shippers and parties.

24. A quarantine is a restriction imposed by duly-constituted authorities whereby the production, movement, or existence of plants, plant products, animals, animal products, or any other article or material or the normal activity of persons are brought under regulation, to prevent or limit the introduction or spread of a pest, or to control or eradicate a pest already introduced, thereby reducing or

avoiding losses that would otherwise occur through damage done by the pest or through costs of continuing control measures.

25. The most significant uses by USDA for chlordane are those involving soil insects under Federal-domestic quarantines. The Plant Protection and Quarantine Programs staff of the Department has quarantine regulations which require treatments, including soil treatments, with chlordane for the Japanese beetle and the imported fire ant.

26. A nationwide survey is carried on each year for the Japanese beetle in the noninfested portions of the infested States and in all other noninfested States, with the exceptions of Alaska and Hawaii. Typically, those infestations found outside of the area of natural spread of the pest are delimited and control measures applied. The most effective adulticide is carbaryl and the only effective and available larvacide is chlordane. Each infestation is evaluated and, if warranted, the Federal quarantine is extended to cover the area of infestation where control measures are not taken or a suppressive area is designated in those cases where suppression or eradication treatments are being applied. If Federal and/or State regulations are imposed on a geographic area, regulated industry is notified and appropriate certification treatments must be applied.

27. For the Japanese beetle, the movement of nursery stock is considered one of the most hazardous articles moving in interstate commerce. Treatments are available to allow movement of plant material not previously treated to meet certification requirements. The most commonly used treatment is either a dip or injection treatment using ethylene dibromide or ethylene dibromide chlordane. This type treatment is an individual plant treatment which is time-consuming, laborious, and costly. The normal sequence of events in applying certification treatments to field-grown nursery stock is to apply a granular formula-

tion of a residual pesticide to ground that had been plowed and disked. After application, the material is disked into the top 3 inches of soil. Three-year certification is obtained by such a treatment. In the case of plant species which are not harvested during a 3-year period, growers often wait until the second or third year after planting and apply chlordane to planted nursery stock free of weeds and follow this application by normal cultivation. In the case of pot or container grown nursery stock, the potting soil is normally fumigated or heat-treated to kill all existing insect life forms as well as weed seeds and other organisms, and the chlordane is added in prescribed amounts to act as a residual insecticide until such container grown stock is sold and moved from the regulated area.

28. Another important method of long distance artificial spread of the Japanese beetle is by aircraft and railroad cars. For some unknown reason, Japanese beetle adults are attracted to aircraft, especially jet-powered aircraft. The large sodded areas of airports are ideal sites for Japanese beetles to deposit their eggs and build up to tremendous populations. Two methods are available to reduce this hazard of artificial spread. If the beetles occur in hazardous numbers and are, in fact, present in airplanes destined for points outside the regulated area, a treatment is available using micronized DDT-carbaryl dust on the interior of the airplane and baggage compartments. This has not been necessary at many airports in the infested area because residual treatments with chlordane and other chlorinated hydrocarbon pesticides have been applied to the turf areas on and around the airport. Retreatment with chlordane may again be necessary. During the early 1970's, milky spore disease was distributed on areas either not previously treated with a chlorinated hydrocarbon or where such treatments were no longer effective. The milky spore treatments have not yet proved effective in reducing populations to nonhazardous levels.

29. The only material currently authorized by the U.S. Department of Agriculture for certification treatments of nursery stock and the regulated items involving soil is chlordane under the Japanese beetle quarantine. The major substiute materials cited by the Environmental Protection Agency may not be suitable substitutes for soil application for Janpanese beetle quarantine purposes.

30. The transporting of nursery stock and certain other soil associated products is also a method of artificial spread of the imported fire ant. The Plant Protection and Quarantine Programs Regulatory Manual currently lists only chlordane or chlordane in association with mirex as a regulatory treatment for sod, nursery stock with soil, and similar items. At this time, there are no alternative treatments available for residual protection against imported fire ants. Treatments of potting soil, nursery stock, or grass sod areas for imported fire ant regulatory purposes are applied in the same manner as the Japanese beetle treatments. After an exposure period of 30 to 60 days, the soil or plants growing therein are certifiable for 1 to 3 years.

31. The black vine weevil is a serious pest of the Japanese yew. The larvae are of particular concern since they destroy the root system of the host resulting in death of the plant. Severe damage to the root system may occur before an infestation is evidenced to the untrained eye. When nursery stock inspected under the State of Michigan's inspection and quarantine authority is found to be infested, movement or sale is not permitted. The Japanese yew, due to its many varieties, persistent green foliage, hardiness, and soil and light intensity adaptability, is the most popular ornamental evergreen planted in the Lake States and the Northeast. Millions are planted around homes, in parks and in industrial landscapes.

32. The black vine weevil is the most destructive and difficult to control of Japanese yew pests. The weevil spreads primarily through the movement of infested nursery stock;

therefore, adequate inspection of nurseries to detect incipient infestations and restrictions on movement of infested plants are highly important. It is also important that a means of eliminating infestations in nurseries and ornamental plantings be available. Currently, chlordane is the only means of control recommended by the Michigan Agricultural Experiment Station. The recommendation is for the application of one pound of actual chlordane in 100 gallons of water as a drenching spray to plants and the soil surface beneath. On the average, such an application would require 200 gallons of the dilute spray or two pounds of chlordane per acre. Granular formulations are not recommended because they have not proven effective. Without chlordane, nurserymen in Michigan having infested and restricted fields of Japanese yews will have no alternative but to absorb a total loss. Presently, an acre of the Japanese yews, 18-inch to 24-inch grade, has a conservative wholesale market value of $20,000. During the last nine years, the Michigan Department of Agriculture has restricted more than 389 acres of yews from sale or movement until weevil infestations were eliminated and certification was possible.

33. The nursery industry includes wholesale growing operations, landscape firms and retail garden centers. Retail sales of the nursery industry for 1971 were $2.1 billion and the wholesale value of these sales was $700 million. In that year expenditures for chemical pesticides used by the industry including insecticides, herbicides and fungicides was $14.8 million. Additional pesticides were purchased, but these were for resale at garden centers. Most pesticide use is at the grower or wholesale level. Pesticide expenditure as a percent of sales to growers was 2.1 percent in 1971. A summary of state recommendations for 15 states indicates that chlordane is recommended for relatively few ornamental insect pest combinations. In several states, it is recommended for only one pest of ornamentals. However,

there are some problems with ornamental pests like the black vine weevil for which chlordane is recommended and for which alternatives are limited.

34. A native of Argentina, Chile, and Uruguay, the whitefringed beetle was first detected in Okaloosa County, Florida, in 1936, in a peanut field. The following year damaging populations were found around Florala, Alabama. Whitefringed beetle larvae so ravaged crops in the limited areas of its distribution in the mid- to late 1930's, that a federal domestic plant quarantine was enacted in 1939 and continued through June 1975 in hopes of stopping the spread of this insect. Despite these efforts, the insect has continued, and will continue to expand its geographic distribution.

25. Three species of whitefringed beetles, *Graphognathus peregrinus Buch.*, *G. minor Buch.*, and *G. leucoloma Buch.* and 5 subspecies have been identified in the United States. Based on limited data, the species appear to be biologically and ecologically similar. All insects examined have been females; thus parthenogenesis (development of the egg without male fertilization) is the mode of reproduction. The insects are univoltine (1 generation/year). Larvae overwinter in the soil, moving closer to the soil surface in spring as they become more active and require more food when temperatures rise. It is during this period that damage to crops planted in the spring, begins to occur. Larvae feed on germinating seeds, on roots, and on underground stems of young plants. Pupation begins at the end of April, reaching a peak during the first 2 weeks of July, depending on geographical location. Eggs are deposited primarily at the point of contact between the soil and objects such as sticks, gravel, and plant stems. The incubation period for eggs oviposited in mid-July to late August averages 14.7 days. Emerging first instar larvae enter the soil and repeat the above described cycle.

36. During the fall, larvae are quite small, and for this reason, damage to the root systems of small grains planted

in fall for pasture or seed has been considered insignificant. This belief was shown to be erroneous. Wet weight yields of Elbon rye harvested in spring were reduced about 50 percent by whitefringed beetle larvae. It is because of their relatively small size during the fall that larvae go undetected even as land is disked after harvest. The larvae continue to develop unheeded until spring when their increased size may give away their presence during soil preparation for planting. It is at this time or during planting that control measures are instituted. The organochlorine group of insecticides are extremely effective against whitefringed beetle larvae when applied during this period. This is true even though these insects are approaching the completion of their larval development, and, as a general rule, the efficiency of insecticides applied against immature stages of insects decreases as the insect approaches maturity. The organochlorine group of insecticides, and particularly chlordane, have had no difficulty in controlling larvae of whitefringed beetle at this difficult-to-control developmental stage. When chlordane is applied at rates of 2.5 to 5 pounds AI/acre "broadcast" protection is extended during the oviposition period of the current year, thus reducing the probability of re-establishment by newly emerging larvae. Alternatively, chlordane may be used to treat rows to be planted. A "broadcast" treatment may be residually effective for as long as 3 years while a row treatment normally will retain its effectiveness for one year. This method of control is the only chemical treatment method available. No alternate insecticide is labelled for control of whitefringed beetle larvae. Alternate methods of control, both chemical and nonchemical, are not currently available as a practical matter.

37. Currently, the whitefringed beetle is distributed throughout Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee. Its greatest infestation is in Alabama, Georgia, and Florida.

The extent of infestation of whitefringed beetle larvae is very difficult to predict and predictions must be based solely upon previous occurrences. The whitefringed beetle attacks practically all field and garden crops. The adult beetle feeds upon the leaves of plants. The adults do not account for a significant amount of economic damage. The larvae, however, are known to feed upon 385 species of plants distributed in 41 plant orders. All significant economic damage is done by the larvae. The larvae eat portions of the soft outer root layer and underlying tissues and may completely sever the main root of the plant. This is particularly common when the beetle attacks small seedling plants. Severe injury to the root system causes the plant to yellow, wilt, and die.

38. The reproductive potential of the whitefringed beetle is very great. Adult beetles may crawl as far as one-fourth mile in their lifetime. The beetles lay eggs from five to twenty-five days after they emerge. The egg-laying period ranges from 30 to 60 days. Adults may live as long as 150 days after emergence, but most die within 90 days. Eggs are deposited in masses of up to 60, but the usual mass contains from 11 to 14. The average length of the larval period is about 10 or 11 months. Some of the larvae hatch in one year. Some do not pupate during the summer of the first year and carry over to the next summer. Larvae generally hatch from eggs in August or September and become adults between May 25th and September 6th of the following year.

39. The peanut industry is the most important agricultural industry in the Alabama and Georgia area, and in the peanut production area of Florida. During the 1975-1976 growing season 200,000 acres of peanuts will be planted in Alabama, 520,000 acres in Georgia, and 55,000 acres in Florida. Total crop values in these states are estimated during that season to total $86 million in Alabama, $302 million in Georgia, and $25 million in Florida. The 1974 Georgia peanut yield was more than 1,670,000,000 pounds which consti-

tuted 40 percent of the peanut production in the United States. During the 1975-1976 growing season, approximate totals of 20,000 acres in Alabama, 26,000 acres in Georgia, and 10,000 acres in Florida of peanuts will be infested with the whitefringed beetle, causing economic loss. Of these, 15,000 acres in Alabama and 13,000 acres in Georgia will not be treated with chlordane even if available. A reason for the increased destruction by the whitefringed beetle is the effective weed control methods which have been developed in the Southeastern United States. Because herbicides are increasingly effective in destroying weeds which grow in peanut fields, the peanut plant becomes its only host. It is very difficult to predict accurately the level of infestation in any given area. In Alabama, it is recommended that growers treat only those fields, or portions of fields, where infestation by adult beetles is present.

40. Between 12,000 and 15,000 people are directly involved in the growing of peanuts in Georgia. Peanuts are by far the most important crop in Georgia. Many related industries, in the supply, processing and distribution phases, are dependent upon the peanut harvest. Thousands of jobs depend upon the crop. Many small towns survive because of the peanut industry. The peanut crop, according to the best estimates available, will significantly increase in 1975. Chlordane and heptachlor are not cited as a recommended treatment for peanuts in Georgia and Virginia, which states account for nearly one half of U.S. peanut production, according to 1975 recommendations. In Georgia, "insurance" treatment with any insecticide is not recommended. If whitefringed beetle problems emerge, growers are encouraged to check with their county agent.

41. The value to Georgia, in terms of income, acreage and yield, of some of the other crops which may be attacked by the whitefringed beetle is as follows:

Crop	*Acreage*	*Yield*	*Income*
Tobacco	75,000	167,625,000 lbs.	$176,519,000
Corn	1,880,000	105,230,000 bu.	171,100,000
Cotton	410,000	200,900,999 lbs.	57,796,000
Soybeans	1,010,000	25,755,000 bu.	161,826,000

Approximately 12,000 to 15,000 persons are directly involved with the Georgia tobacco industry. An equal number grow cotton. As many as thirty to forty thousand Georgia citizens grow corn, and an equal number grow soybeans. As with peanuts, thousands of workers are employed in related supply, processing and distribution industries. In addition, truck crops produce an annual income of more than $76,000,000 in Georgia, but no acreage or yield estimates are available. Chlordane may be used in the planting of all of these crops in much the same way it is used to treat peanut acreage. The soil is treated before planting. However, diazinon may be used in the treatment of tobacco. Diazinon can be mixed with the water used in the transplanting of the tobacco plant. Diazinon is effective for a shorter period of time than chlordane.

42. Florida produces over 75 percent of the United States' supply of citrus, which represents approximately 28 percent of the world's supply. Citrus is grown on 877,000 acres and is by far the most important agricultural commodity grown in the State of Florida. Florida citrus has an annual value of near one billion dollars.

43. There are 7 weevils considered pests of citrus in Florida, all but one having in common an immature stage that feeds on citrus tree roots. The exception, the Coffee Bean Weevil, *Araecerus fascilculatus* (DeGeer), attacks the fruit itself. The 6 root-feeding pests of Florida citrus are the Little Leaf Notcher, *Artipus floridanus* (Horn), the 2 Citrus Root Weevils, *Pachnaeus litus* (Germar) and *P. opa-*

lus (Olivier), the Fuller Rose Beetle, *Pantomorous cervinus* (Boh.), the West Indian Sugarcane Stalk Borer Weevil, *Diaprepes abbreviatus L.,* and *Tanymechus lacaena* (Hbst.,), a species lacking a common name. The Little Leaf Notcher was first reported on limes on the Florida Keys and is now distributed along the east coast as far north as Merritt Island. The Citrus Root Weevils have been associated with citrus in Florida for over a century. Prior to 1885, *P. opalus* adults were caught in great numbers on the Keys and by 1966 had been collected in 21 counties. *P. litus* distribution was reported in 1825 as ranging from Cuba to Florida and by 1966 had been collected in 21 Florida counties. Immatures were identified in the soil in 1915. Fuller Rose Beetle was recognized as a pest of Florida citrus in 1952 when large numbers were observed in several groves in Indian River and St. Lucie counties. Since that time, this pest has been collected from 30 counties in the State. The West Indian Sugarcane Stalk Borer Weevil is the most recent intruder, being found initially in 1964 and becoming established in 1969 near Apopka, Florida, where it was confined until recently within a 16,000-acre quarantine zone regulated by the U.S.D.A. and the Florida Department of Agriculture and Consumer Services.[10] *Tanymechus lacaena* was first recorded for Florida in 1921 and has only posed an occasional problem in newly set groves.

44. The life cycle of all 6 root feeding species adheres to the 4-stage pattern inherent in beetles: the egg, larva, pupa, and adult. Eggs are deposited above ground and larvae

[10] Chlordane and heptachlor are not registered for control of the West Indian Sugarcane Stalk Borer Weevil, and, therefore, their use to control this insect is beyond the scope of this proceeding. Some question exists as to whether these insecticides are registered for use against the Fuller Rose Beetle, apparently the major soil pest of citrus, although they were used for this purpose. This need be resolved by administrative officials. To place matters in perspective, it should be stated at this point that the Fuller Rose Beetle is a minor pest of citrus.

enter the soil to feed on roots. Pupation occurs in the soil and adults emerge from the soil to remain above ground feeding on foliage, mating, and laying eggs. All 6 species are presently considered univoltine: producing but one generation per year. The adults feed on the young leaves of citrus and, when in great numbers, cause serious setback of young trees. With the exception of *Tanymechus,* for which no observations are recorded, adults also feed on the flowers and on rind of young fruit, resulting in peel scars when the fruit matures. Occasionally, young shoots are devoured. The most serious injury by the pests is produced by the larvae which destroy the plant roots. Affected trees have sparse foliage that may become chlorotic and wilt. When larvae are numerous, young plants may be killed in a short time or dwarfed; older trees are more resistant, but do not grow well, are unthrifty in appearance, become poor yielders of fruit, and occasionally die. Since the damage caused by the larvae takes place underground, it often remains unnoticed until the plants start to wither and 'die black.'

45. A variety of methods, including mechanical control, biological control, chemical control, and cultural practices have been attempted over the years to control the Fuller Rose Beetle. Methods such as hand picking egg masses and adults, trunk banding and such practices as root barring were of temporary value and required continuous surveillance. Chemical control required 4 to 6 foliar applications to achieve season-long control. No method gave the control of the weevil pests provided by soil application of the insecticides chlordane or heptachlor. The recommended program today for controlling the citrus weevil complex is a soil treatment with chlordane or heptachlor and is based on the fact that adults must, when emerging from the soil, pass through the toxic barrier created at the soil surface upon application of these insecticides. Newly hatched larvae may also be killed when attempting to enter the treated soil. Although 2 distinct periods of peak emergence occur

in the spring and fall, adult weevils will emerge from the soil throughout the year in Florida.

46. Florida's integrated pest control programs utilize a combination of both biological as well as chemical methods to control citrus pest infestations. The biological control consists of several parasitic and predatory insect species which have been introduced into the citrus groves. These predatory insects control aphids and scale insects. The purple scale was at one time Florida's number one pest in citrus. Soil applications of chlordane or heptachlor do not harm the beneficial predatory and parasitic insects. The only alternative to soil applications of chlordane or heptachlor is multiple foliar spraying to kill adult beetles. This would require 4 to 7 foliar spray applications of insecticides per year. Soil applications of chlordane or heptachlor on the other hand are only required every two to three years for the same control. The increased foliar applications would be disruptive to the Florida citrus integrated pest control program. The foliar applications required would kill the beneficial parasitic wasps which have been introduced into Florida's citrus groves. These wasps are today relied upon heavily for the control of scales and mites. The introduction of these beneficial insects have greatly reduced the use of pesticides in citrus cultivation. Scale insects, which are under biological control as a result of these introduced predators and parasites, could once again become serious economic pests with their natural enemies killed off by frequent foliar pesticide applications.

47. Without an effective soil insecticide, the only option for beetle control is increased spraying of organophosphates to control adult beetles as they migrate from the soil to the foliage of trees. This option would probably not provide the same level of control. Soil insecticides provide maximum protection to citrus groves by interrupting the life cycle as the larvae migrate to the soil and by providing control over the number of adults who can move from the soil back

to the foliage. Foliar sprays can be effective in reducing the adult beetle population at the time of application and shortly thereafter; however, because of the variability of the life cycle of the target insects, quarterly foliar applications would probably be required. In this event, the entire spray schedule would have to be restructured together with modifications in the current biological control programs.

48. If left uncontrolled, the damage caused by the Fuller Rose Beetle could be severe with impacts distributed unevenly across the citrus growing regions of Florida. Citrus District Five, made up of Atlantic Coast counties including Brevard, Indian River, St. Lucie, Martin, Palm Beach, Broward, Dade, and portions of Volusia is characterized by groves planted on artificially constructed beds, surrounded by draining ditches, which were once partial swamp land. High water tables limit the depth of the root systems; 90 percent of the roots are often concentrated in the top 18 inches of soil. In the central part of Florida, citrus roots can penetrate up to twenty feet and average twelve to sixteen feet. In the coastal counties, a greater portion of the root system is available for larvae feeding. Thus, the same level of beetle infestation can result in greater damage for these trees than for inland groves. Disking in the inland groves to a depth of 6 inches around the trees may interrupt the pupation stage of the beetle thereby providing marginal, non-chemical control. In the coastal regions, disking to this depth would severely damage the root system. Without cultivation, grass and weeds compete with the tree for available moisture. For this reason, coastal groves are more susceptible to drought which in turn exerts a stress on the tree and leaves it more susceptible to damage by any factor that reduces the root system.

49. Without adequate control of root feeding beetles, citrus production in coastal counties could prove unprofitable for many groves. Using treatment history as a base to define infested acres (and assuming that treatment is made

every three to five years), 25 percent of Florida's East Coast county citrus acreage could be subject to root damage if adequate control of soil beetles is unavailable. As a percentage of total Florida citrus, this coastal county acreage would affect approximately 6 percent of current citrus production (1972 base).

50. Because of an inelastic demand for citrus at the farm level, the market impact of a decrease in production would be an increase in farm level income to citrus growers in the aggregate. However, due to the greater potential for insect damage in the East Coast region, these growers could be subject to income reductions if an adequate control agent is not available. Due to currently low income levels and a lack of alternative employment, a significant production decline would cause significant social impacts.

51. In 1976, about 8,000,000 new citrus trees will be planted in Florida. This planting will be for the purpose of replacing dying trees as well as starting new groves. Areas of new planting in Florida may be subject to subterranean termite attack. Chlordane or heptachlor are used to protect these newly planted trees.

52. California use of chlordane on citrus is directed primarily at control of the Argentine ant which interferes with natural predators of scale insects. It has been estimated that 25,400 pounds of chlordane were used on 8,112 acres (3.2 percent of California citrus acreage) during 1973. A five percent granular chlordane compound applied either aerially or with ground equipment at a rate of 100 pounds per acre was the typical dose against Argentine ants during this period. Substitute control programs use two to four ground applications of diazinon for one application of chlordane or foliar sprays to directly control scale insects. One or two foliar applications of either parathion, malathion, carbaryl, guthion or supracide would be needed as an effective substitute for the chlordane treatment. Only a

small proportion of the California citrus acreage (3.2 percent) requires treatment for control of Argentine ants and the substitute control program has a small effect on citrus production costs. The direct regional and national impacts associated with a restriction in chlordane use for California's citrus industry are expected to be small. The impact of suspending this use would be felt primarily by the grower. Such pesticides as parathion could upset pest management programs and require a reorganization of foliar spray schedules.

53. Seed treatment is used to decrease stand loss attributable to seed eating insects. It is intended to protect grain and vegetable seed up to the germination period. It is estimated that between 4 and 8.7 percent of all grain seed (1970-1974) was treated with heptachlor in five midwestern states. Similarly, between 8.6 and 20.2 percent of all seed was treated with one of five major insecticides including heptachlor. Estimates are not available on the intensity of seed insecticide treatment in other agricultural areas. Velsicol Chemical Corporation estimates that about 269,000 pounds of heptachlor were used for seed treatment or dressing in 1974.

54. Seed treatment provides temporary protection from seed eating insects (seed corn maggot, seedcorn beetle, thief ant, wireworms and false wireworms) during germination. Major protection from heavy infestations is provided by more costly and intensive soil treatments. Seed treatment alone does not provide adequate protection under such conditions. Commercial seed producers generally do not now apply insecticides to seed for protection during germination. For many types of seed the alternative to commercially treated seed is planter-box or drill-box treating by the farmer. These treatments are generally formulated with from 12½ to 25 percent active insecticide and, almost without exception, contain a lubricant such as agricultural grade graphite. Suspension of heptachlor seed treatment would

generally result in the use of lindane, diazinon, or a combination of lindane/diazinon. State recommendations consistently recommend the above as seed treatment alternatives to heptachlor. However, supplies of lindane are scarce and a substantial portion of the heptachlor seed treatment use could not be made up by lindane. For diazinon the outlook is somewhat better as the volume needed for seed treatment is small compared to total diazinon use.

55. Resistance of seed feeding insects to cyclodiene insecticides is prevalent in certain geographical areas. Seed corn maggot and slender seed corn beetle, for example, are resistant to aldrin, chlordane and heptachlor over the northern and east central areas of Missouri. Iowa no longer recommends chlorinated hydrocarbons in the state because of resistance in these insects. Illinois notes that, among other insects, seed-corn beetles, seed corn maggots and possibly wireworms are no longer effectively controlled by chlorinated hydrocarbons (lindane is included in this group).

56. Lack of efficacy and phytotoxicity data for diazinon prevents an accurate appraisal as to whether that chemical will be a good seed treatment substitute for heptachlor under all conditions. As with lindane many factors may affect its performance as a widely used seed protection.

57. Heptachlor removal as a seed treatment is most troublesome primarily in the Southwest. It is estimated that removal of heptachlor as a seed treatment may result in a financial loss of greater than $22 million dollars in the State of Texas. This estimate includes only the cost of replacing and replanting sorghum, small grain and corn seed. Seed replacement estimates vary between 10 and 20 percent of the planted acreage dependent upon crop. Further detailed economic assessments of additional loss due to reduction in yield of quality or quantity have not been made. Wireworms are the major seed eating insect problem in Texas. Diazinon seed treatment is considered to be generally ineffective on wireworms. Though recommended as an alternative to

heptachlor seed treatment for seed corn beetles, seed corn maggot and wireworms on corn and small grains, lindane is reported to cause various degrees of phytotoxicity particularly on sorghum. Neither chemical is considered to be an effective seed treatment alternative in the Texas grain producing areas. Cultural techniques are not believed to offer protection against seed eating pests. Planting dates cannot be delayed due to either climatic conditions or to the presence of other pests that can attack at other vulnerable stages. Potential control from rotation is limited by the fact that many grain growing areas in Texas are not adapted to crops other than grains. Additionally, cotton/grain and cotton/sunflower rotations in other locations are not always plausible as the market for cotton may be uncertain and sunflower seeds are a crop of limited demand. Insect infestations often exhibit densities directly proportional to the seeding rate, therefore, an increase in the rate of seeding will not necessarily produce the desired stand.

58. Low to moderate populations of wireworms are effectively controlled by heptachlor seed treatments of .175 to .25 ounces of active chemical per bushel of seed. Planter-box applications of heptachlor formulations including .5 to 1 ounce of active chemical per bushel of seed have been equally as effective provided lubricants of some sort are included in the formulation to remove the "planter drag" of the added material so that uniform, expected seeding rates are obtained. One bushel of seed is sufficient to plant 3 or more acres of corn. Sorghum seed treated at one-half to one and one-half ounces of actual heptachlor per 100 pounds of seed will plant from 10 to 25 acres.

59. The Pacific Northwest is the production center of narcissi, more commonly known as daffodills. Both bulbs and cut flowers are distributed nationally. The narcissus bulb fly is the principal insect pest of daffodils. Narcissus production is a small acreage industry, but one that has high per acre gross monetary value. Approximately 1800 acres

are grown in the United States with the major production centers located in Washington, Virginia, New Jersey, California, North Carolina and Oregon. Income is derived from dry bulb sales, field-cut flowers and forced greenhouse flowers. Washington and Oregon are the major supply sources for dry bulb sales. Total value of the crop in these 2 states approaches $2,000,000 annually.

60. Narcissus production is concentrated in geographical areas with comparatively mild climates where winter and summer extremes are tempered by winds from large bodies of water. A normal cropping season extends from August to the following July. Bulbs are planted to fields in rows during August and September with specialized machines that set the bulbs uniformly spaced in deep furrows (6''-8'' below the soil surface) which are then covered with drag-bars or discs. Rows are hilled periodically to control weeds, facilitate drainage and protect the bulbs from freeze damage. In the late fall chemical weed killers are applied to suppress weeds until the following spring when the soil dries out enough to permit cultivation and post-emergence herbicide applications. The bulbs sprout in late fall and foliage emerges during mid-winter. Daffodils usually bloom in late March or early April, depending upon the weather and location. Cut flowers are harvested at bud stage from some fields in March. The flower heads from nonharvested fields are removed to maximize bulb growth. Fields are rogued once or twice in the spring to remove off varieties and diseased plants. Irrigation is often provided in May and June to increase bulb yields. Harvesting commences in July after the plants have matured and the tops have died back. Bulbs are mechanically dug with grower-designed and constructed machines which resemble potato diggers, but contain additional components for preliminary field cleaning and grading. Bulbs are stacked in trays and field cured for 7-10 days. They are then transported to sheds where they are artificially cured, cleaned, graded and treated with

chemicals for protection against disease, nematodes and insects. Bulbs are graded into planting stock and various sizes for sale.

61. The principal insect pest of daffodils is the narcissus bulb fly, *Meredon equestris*. It occurs wherever bulbs are grown in Europe and North America and causes more trouble than all other narcissus insects combined. While mainly a pest of narcissus, it also attacks amaryllis, hyacinths, lilies, tulips and other bulbous plants. The flies, which resemble bumble bees, are present from the middle of April through June in Washington. Females lay separate eggs on the foliage or soil near the base of the plants. Eggs hatch in 10-15 days, and maggots, which are the destructive stage of this insect, move downward to the base of the bulb where they enter the bulb through the basal plate. The larvae feed on the interior of the bulb and eventually create a cavity filled with soft brown decayed tissue. The larvae develop to mature size, about ¾ inch long, by late September or October. Larvae remain in the bulbs during the winter and leave them in March to form puparia in the soil. Flies emerge from the puparia in late spring and begin the cycle again.

62. Since the 1950's narcissus growers have effectively controlled the bulb fly with heptachlor bulb dips prior to planting. The bulbs are usually soaked from 10-60 minutes in emulsions containing 0.8 pounds of heptachlor per one hundred gallons of water. Bulb dips are an economical and highly effective means of controlling the bulb fly on narcissus. The heptachlor bulb dip is the standard control measure wherever the pest is an economic problem. No practical alternative to heptachlor exists at this time. Chlordane is also an effective material as a bulb dip for the fly. However, this material was never recommended for commercial use because it was incompatible with the mercuric fungicides that were used in the dips for protection against bulb rots. In recent years mercury fungicides have been replaced with a modern organic fungicide, Benlate. Data are avail-

able which indicate that chlordane and this fungicide are compatible in the dipping tank. Several new insecticides show promise as bulb dips and may eventually become practical alternatives to heptachlor. The long-term impact of a heptachlor suspension or cancellation appears less serious than the immediate effect of such an action because potential alternative insecticides as bulb dip treatments do exist.

63. The adults (or June bugs) of the white grubs lay their eggs in soil, in sod, or in grassy fields. The larvae (called grubs) that hatch from these eggs feed primarily on the roots of the grasses. The grubs will feed for two or three years, depending on the species. When the field is broken for planting, the grubs will feed on the roots of any crops planted in that field. Their feeding can destroy the stand and weaken plants, thus reducing yield. The grubs are rarely distributed evenly across a field, and their damage usually appears as variously sized circular areas of poor stand surrounded by stunted plants. Also, the root damage caused by the grubs makes harvesting difficult. Grub damage has occurred throughout the State of Michigan, but most of the problems have been in the heavier soils in the southern half of the Lower Peninsula. Grub problems increase with an increase in opening of fallowed fields.

64. Good control of grass weeds in crops and maintenance of high vigor in forages is emphasized as a means of keeping grubs down in tilled land. An increased threat of insect damage occurs in fields recently removed from sod or heavy weeds. It is recommended that growers check plow furrows for white grubs when they are fitting their lands. There is no hard criteria for deciding when grub control is needed, but it is recommended that the field be protected from grubs when the grubs are easily found in the field. Treatments are not recommended unless the grubs can be found in the field because not all sod fields are heavily infested with grubs. Sometimes grubs are not detected until after the plants have emerged. The affected areas are treated, disked

and replanted when there is time. This reduces the loss but increases the cost of control.

65. The alternative to chemical control of grubs is clean fallow of the land for one year following breaking it from sod. This removes the land from production for that season. Clean fallow leaves the land open to wind and water erosion.

66. A broadcast application of chlordane and mixing the insecticide into the upper layer of soil prior to planting is recommended for grub control. The insecticide can be applied as a spray or as granules. Broadcast granular applicators are scarce in Michigan, and most of the applications are made using weedkiller type sprayers. The mixing can be done by the disking before planting and is recommended to prevent decomposition of the insecticide by the sun and hot surface of the soil, to reduce exposure of wildlife to the insecticide, and to reduce run-off. The broadcast application rather than a band application is required for control of grubs. Soil fumigation, recommended in some states, is exceedingly rare in Michigan.

67. The State of Michigan currently recommends 4 pounds active insecticide per acre of chlordane, parathion, or diazinon for white grub control in field crops. Parathion and diazinon were recommended to have something to reduce the losses caused by white grubs in those crops where chlordane cannot be used. Their lack both of specificity and residual effectiveness have given acceptable control only in re-plant situations. Two newer insecticides, Lorsban and CGA-12223, are reported to be promising for white grubs, but they are still unproven.

68. The economic impact of a ban on chlordane in field crops in Michigan would not be major on a state-wide basis; however, the economic impact on a number of farmers would be very significant. The estimated acreage infested annually in Michigan is corn, 10,000 acres; small grains, 5,000 acres; soybeans, 3,000 acres; and dry beans, 2,000 acres.

69. Growers in New York State annually produce approximately four million pounds (two and two-thirds million quarts) of strawberries. The annual value of this crop at present is estimated to be at least 1 and ⅓ million dollars. Among the insects most difficult to control in a strawberry planting are those that spend their immature or larval stages feeding on the crowns or on the roots. Plants attacked by these species usually die or at least remain stunted and nonproductive. In New York State there are at least five species of insects that may, and when not controlled often do, injure the crowns and/or roots of strawberry plants. The most important species involved are: white grubs—*phyllophaga sp.*; strawberry rootworm—*Paria canella* (*Paria fragariae*); strawberry root weevil or crown girdler—*Brachyrhinus ovatus (Otiorhynchus ovatus)*; black vine weevil—*Brachyrhinus sulcatus*; and strawberry crown borer—*Tyloderma fragariae.*

70. Strawberry plants are set in the spring in rows 4 feet apart with the plants about 18 inches apart in the row. These plants multiply by sending out runners which produce daughter plants to develop each row into a bed approximately 3 feed wide. No crop is produced the first year. Crops are produced the second year, and possible for 6 or 7 additional seasons, depending on cultural practices and the degree of weed, insect, and disease control obtained. Presently, some growers plan to fruit their beds 4 to 6 years.

71. The use of preplant soil treatment of a persistent insecticide protects the plants against the feeding of root destroying insects species for several years. In the Northeastern United States and Eastern Canada, chlordane is generally, and in most cases the only, recommended material for this purpose. Chlordane is specifically recommended in Minnesota, Michigan, Ohio, New York, Connecticut, Massachusetts, Maine, Vermont, New Jersey, Maryland, West Virginia, and in Ontario, Canada. New York State recommends the use of chlordane in strawberry production only if the land utilized had previously been in sod. The chlordane formulation is incorporated in the upper 3 to 6 inches of soil before planting for the control of white grubs and other root-feeding species.

72. The larvae of rootweevils and white grubs are serious pests in certain areas for which several states recommend chlordane and for which alternative controls are limited. Other chemicals such as diazinon and carbaryl reportedly are effective controls but are not registered at sufficiently high rates of application to provide effective control. Most California production, which equals ⅔ of the U.S. total, would not be affected. In 1974, chlordane was used on only 16 percent of 1974 acreage grown (8,300 pounds on 1,409 acres). The next four ranking states in terms of commercial strawberry production would be adversely affected at least to some extent. They are, in terms of percentage of United States strawberry production, Oregon (10 percent), Washington (5 pecent), Michigan (3 percent) and North Carolina (1 percent). If alternatives are unavailable for control of these pests in these commercially important production states significant national impacts would occur on the production of strawberries. The extent of economic impact of shifting to alternative crops for affected growers is not known at this time. The impact of shifting to alternatives is minimized to some extent in the state of Washingon since neither chlordane nor heptachlor currently provide consistently effective control over the weevils attacking strawberries in that state. The lack of alternatives is likely to have production impacts also in Kentucky, Maryland, Missouri, Mississippi, Nevada, New York, Ohio, Tennessee and Wisconsin.

73. Hawaii is the world's largest producer of pineapple. The canned pineapple production in 1974 of 7.9 million cases represents 28 percent of the total world production. The gross income reported from the production of pineapple in

Hawaii in 1974 amounted to 124.3 million dollars. Hawaii's pineapple, grown on 43,300 acres, employs approximately 3,700 people year around and an additional 7,000 during the peak of the season. The Hawaiian pineapple industry has experienced a decline in recent years.

74. The mealybug wilt disease is a highly devastating malady of pineapple. The affected plants do not produce marketable fruit. If no control measure is applied, the disease can spread rapidly and extensively, often over the entire field. The Hawaiian pineapple industry suffered a tremendous loss years ago from this disease prior to the development of effective control measures.

75. Mealybugs are the principal cause of mealybug wilt. Mealybugs suck sap from the pineapple plants. If the mealybugs are not controlled, the root systems of the pineapple plant will collapse. Ants have a commensal relationship with mealybugs. Ants carry mealybugs to and from pineapple plants, particularly from the wild growth in the outfield area to pineapple plants in the field, and ants attend or protect mealybug colonies on pineapple plants. All mealybugs excrete a sweet-tasting product referred to as honeydew. Ants particularly have developed the capacity to exploit honeydew as a food resource. Certain ant species such as the big-headed ant, *Pheidole megacephala* (Fabricus) and the Argentine ant, *Iridomyrmex humilis* (Mayr), aggressively seek out honeydew producers such as mealybugs. The active solicitation of honeydew by ants increases the volume of sap imbibed and the amount of honeydew produced by individual mealybugs. In Hawaii heavy populations of mealybugs are associated with attendant ants. Elimination of these ants allows natural enemies, such as predators and parasites to greatly reduce mealybug infestations. In the absence of ants, the mealybug becomes surrounded with masses of honeydew which is a substate for fungi that will cover and eventually kill the mealybugs.

Mealybugs on pineapple can be largely controlled by eliminating the ants which tend them.

76. The major ant species in the Hawaiian pineapple fields are principally the big-headed ant and the Argentine ant. The principal mealybugs associated with pineapples in Hawaii are the pink pineapple mealybug, *Dysmicoccus brevipes* (Cockerell), and the gray pineapple mealybug, *Dysmicoccus neobrevipes* (Beardsley).

77. Heptachlor is effective for the control of ants in Hawaii's pineapple fields. Heptachlor may be applied to the soil at a rate of one to three pounds of active ingredient per acre and as a foliar spray for the control of the ants at a rate of one to two pounds of active ingredient per acre. Applications of this chemical may be made at monthly intervals to the foliage for as long a period as is required provided that it is not applied within 60 days of harvest. Chlordane also will give effective control of the ants. However, by label restrictions it can only be applied to the soil and only when there is no fruit present.

78. The only registered alternative for the control of ants in pineapple in Hawaii is mirex. Mirex, as a broadcast treatment of pineapple fields, may be applied only once in any twelve-month period. Mirex is applied at the rate of 2.5 pounds of Harvester Ant Bait "300" which contains 3.4 grams of active ingredient per acre per year. Wet ground or rain may make the bait worthless as an ant control measure. Oil in the bait is the attractant and moisture washes the oil out of the bait. Heptachlor can be used under those weather conditions where rainfall has rendered the mirex treatment worthless.

79. Without the control of ants the spread of mealybug wilt can accelerate and the commercial growing of pineapple could be in serious jeopardy. Mealybugs, as distinguished from the ants, can be partially controlled using diazinon or malathion. Mealybug infestation at subterra-

nean level, however, cannot be reached with these insecticides. Without ant control, mealybug control by these two chemicals would be only a temporary restraint on the rapid acceleration of wilt.

80. An estimated 6,000 to 8,000 pest control firms throughout the country have one or more full-time employees. The type of work conducted by the pest control industry is commonly referred to as structural pest control and involves the control of several hundred potential pests. Only a few dozen are regularly encountered. In turn, three specialty areas of structural pest control are recognized in the industry: *Termite control* including the control and elimination of wood destroying insects such as termites, powderpost beetles, old house borers and carpenter ants, in addition to the control of wood destroying fungi; *General Pest Control,* including the control of rats, mice and the common household insect pests such as cockroaches, ants, fleas, ticks, silverfish, food and pantry pests, fabric pests and occasional intruder from out-of-doors; and *Fumigation,* which may be a specialty in itself in either the termite or general pest control area depending on the problems in any given area.

81. Chlordane, first used commercially in 1946, came into broad scale use by pest control operators after 1950. Since that time the pest control industry has used chlordane to control a broad spectrum of household and wood destroying pests. Many efficacious substitutes or alternatives to chlordane exist for use against household pests, as recognized by the National Pest Control Association itself.

82. Carpenter ants of the genus *Camponotus* occur widely in North America and are the largest of our common ants. The adults vary in length from about ¼'' for a minor worker up to ¾'' for a queen. They are either black or black and red in color. They do not eat wood but excavate extensive galleries in logs and timbers to serve as nesting sites. Carpenter ants are being reported with increasing frequency as a serious household pest and wood-destroying insect.

Carpenter ants are omnivorous in their food habits, that is, their diets include a great variety of both animal and plant foods. Most of the carpenter ants' animal food consists of insects and other small invertebrates living or dead. Many sweets and meats commonly found in kitchens and food storage areas in structures are attractive to these ants. A number of different ants utilize cavities in wood as nesting sites; however, only carpenter ants cause sufficient damage to timbers by their extensive mining to be of economic importance. Although the nest is most often begun in soft, decaying wood, subsequent excavations frequently are made into sound and dry lumber. Unlike termite workings, the walls of the carpenter ants' nest are smooth and clean, having a sandpapered appearance. When carpenter ants are found in a structure, either the colony is nesting within the building proper, or they are nesting somewhere outside the structure and merely entering to forage for food. A 2 or 3 percent water emulsion or oil solution of chlordane applied as a spot treatment may be used. Dusts of 5 percent chlordane may be used in infested areas instead of, or in conjunction with, sprays. Dusts are particularly effective for treating the nest galleries. The gallery injection method of applying chlordane is generally used in treatment of carpenter ant infestations. In that case, liquid chlordane is injected directly into the insect-created cavity.

83. There are true powder-post beetles (Lyctidae), false powder post beetles (Bostrichidae), deathwatch and furniture beetles (Anobiidae) and old house borers (Hylotrupes bajulus (l.)). Insects in this group have the following common characteristics: they infest cured, even kiln-dried wood; they reinfest wood over and over again; their feeding takes place within, not on, the surface of wood; their larvae, which do virtually all of the injury to wood, work independently of one another and bore through the wood in an aimless fashion; and wood is chewed by a scraping or rasping action

of the jaws at the head end of the insect, is partially digested in the insect's gut and then is discharged into a tunnel behind the larva as a fine powder of only slightly altered wood.

84. Among the many different kinds of insects that attack wood and wood products, the destructiveness of lyctid beetles is rated second only to that of termites. Their activity causes many millions of dollars' worth of damage in the United States each year. Lyctids are a pest primarily of the sapwood of hardwoods and are more commonly found in recently dried rather than old wood. They are found infesting hardwood flooring, hardwood timbers, plywood, crating, furniture, tool handles, gun stocks, and many other specialized wood articles. Their attack is characterized by the reduction of sound wood to fine powder. Anobiid powder post beetle infestations are common in softwood framing—especially floor joists of crawl space buildings. They are common in the southeastern part of the country. Bostrichid powder post beetles are more prevalent along the west coast. Some are of moderate size up to an inch in length. The old house borer may attack ancient structures and a building may be many years old before the attack is discovered, but this moderate sized beetle most often attacks new structures in the United States. The old house borer has a very long life cycle and can infest the same piece of wood again and again. In the United States, the old house borer has become well established in most of the states along the Atlantic coast. Chlordane treatment for powder post beetles is generally limited to relatively few areas within a structure, normally areas of restricted access. Areas of common infestation are: substructures, framing, subflooring, attic framing and hardwood floors. Treatment is confined to the wooden member itself as it constitutes the insects' entire habitat.

85. Ticks and chiggers are pests to the human population, and some of the ticks are also vectors of serious illness in

the south-central region of the United States, including Arkansas, Louisiana, Oklahoma, Missouri, and Texas. Eighteen species of ticks are known to presently occur in Arkansas. Those which are most common attack man. These are *Amblyomma americanum,* the lone star tick; *Dermacentor variabilis,* the American dog tick; and *Ixodes scapularis,* the black legged tick. These are the three most abundant species. The lone star tick extends from Central Texas to the Atlantic Coast and northward to Iowa and Maryland. Ticks attach themselves to warm blooded animals, including man, for the purpose of sucking blood from their host. In so doing, they inflict severe bites, which frequently are accompanied by swelling and infection.

86. In addition to the pest aspects, the hazard of contracting tularemia or Rocky Mountain Spotted Fever from ticks is present. Tularemia is primarily a tick-borne disease in Arkansas. In Arkansas 56 percent of 704 cases were attributed to tick bite. Tularemia is a debilitating ailment that leaves its victim suffering through a long period of convalescence unable to work effectively. This disease may also result in death to the individual. Rocky Mountain Spotted Fever is another disease that is specifically tick-borne. The American dog tick, *Dermacentor variabilis,* is a proven vector of this disease. This tick is the second most frequently occurring species. The lone star tick, *Amblyomma americanum,* which is the most abundant tick, is also a vector for this disease. Because dogs are commonly carriers of the dog tick, this disease agent is brought in intimate contact with the home environment and particularly children. Moreover, dogs themselves become infected and, in turn, infect additional ticks, thus increasing the exposure hazard.

87. More cases of Rocky Mountain Spotted Fever occurred in the United States during 1974 than in any previous year since definitive records have been maintained—a total of 774 cases have been reported to the Center for

Disease Control. Rocky Mountain Spotted Fever is not confined to the Rocky Mountain area. In 1974, as in previous years, more cases occurred in the southeast than in the Rocky Mountain region. There were more cases in single states, such as Virginia, North Carolina, South Carolina, Georgia, Alabama, Tennessee, Arkansas, Oklahoma, and Texas, than in the entire Rocky Mountain region, where only seven cases were reported. Since 1960 tick-borne typhus or Rocky Mountain Spotted Fever has been reported in all the contiguous states except Maine, Vermont, Alaska and Hawaii.

88. In Arkansas, heptachlor and chlordane are not recommended for use against ticks on animals, such as beef cattle, dairy cows, horses, sheep, goats and dogs or interior or exterior household use against ticks and many other insecticides are recommended instead. For outdoor use around the home against chiggers, chlordane, diazinon and heptachlor are recommended and for tick and chigger control in recreational areas, heptachlor and diazinon are recommended.

89. Harvester ants are common ants often present in large numbers throughout the more arid areas of the Western United States. They are more numerous during drought years but cause problems every year. Their large mounds are found in recreation and other areas where vegetation is scanty such as school yards, playgrounds, roadsides, animal trails, and lawns which have patches where grass is not plentiful. Harvester ants also may be serious pests of alfalfa fields, recently planted orchards, pastures, and meadows, particularly during drought periods.

90. When nests are established where people frequently come in contact with them, the harvester ants may become a health problem. The effects of a sting can be very painful. Localized swelling and inflammation ensue rapidly. Soon thereafter a throbbing pain which may last for several

hours extends to the lymph nodes of the inguinal, axillary, or cervical area, depending on the location of the sting. Multiple stings will produce excruciating pain and may induce systemic disturbances of considerable severity. Victims who are hypersensitive to the ant venom may collapse from anaphylactic shock and be in danger if not given prompt medical attention.

91. The swarms of reproductive harvester ants (Pogonomyrmex) which occur during the summer months may cause inconvenience and harm to those who are involved. Usually after a heavy rain during the summer the worker ants stop their harvesting activities and become much more aggressive. Animals encroaching upon the cleared area of the nest are driven off if possible, smaller animals are killed but not brought into the nest. Soon the winged ants (queens and kings) leave the nest and fly to an open area such as the roof of a building, parade ground, tennis court or other clear surface found at the highest elevation in the vicinity. Thousands of ants gather as a moving mass 6-8 inches deep. The swarm may remain in the area for several hours. All human activities in the swarming area are stopped. In cropland, once the harvester ants have developed a well established nest, the ants carry off seed necessary for revegetation of pasture. The seed is sorted in nest galleries extending as much as 15 feet below the surface. Long term alternatives to chlordane for use as a bait against the Texas harvester ant or Pogonomyrmex barbatus is apparently currently lacking.

92. Imported fire ants both sting and bite their victims. The imported fire ant attacks its victim by grasping the skin with its mandibles, or jaws, pulling on the skin, pinching it, doubling its abdomen forward and driving the stinger located at the hindmost end of the abdomen into the skin. The imported fire ant maintains this position for many seconds, usually 20 or 25. A poisonous venom is injected through the stinger into the skin. Grasping of the skin by

the mandibles is the "bite" of the imported fire ant. The injection of venom into the skin of the victim through the stinger is its sting.

93. The pustule appearing at the site of the sting is sterile. The venom of the imported fire ant is poisonous not only to human tissues but also to bacteria and fungi. However, the fluid and skin membrane, plus the maintenance of the dead tissues at body temperature create an incubator for microorganisms able to enter the pustule resulting in secondary infection, which is probably the most common problem arising from an imported fire ant sting. Persons who are allergic to components of the venom of the imported fire ant sometimes develop massive swelling in the vicinity of the sting. Large blisters sometimes form at sting sites and bleeding into the blisters sometimes occurs. Imported fire ant stings sometimes cause a chronic spreading skin condition called infectious dermatitis. This occurs frequently when persons are stung on the lower extremities.

94. A small percentage of the population exposed to imported fire ant stings or the stings of other venomous insects, such as bees and wasps, develops a sensitivity to the venom which results in anaphylactic shock. Anaphylactic shock is a critical and life-threatening condition, accompanied by difficulty in breathing and decrease in blood pressure. Fatalities caused by imported fire ant stings are most likely to result from anaphylactic reactions. If a person who has seriously impaired circulation to his or her extremities, for example, due to arteriosclerosis, is stung on the hand, arm, foot or leg by imported fire ants, the tissues inadequately supplied by blood tend to heal poorly. Secondary infection is more likely to occur and may result in gangrene developing. If the blood supply cannot be improved, it may be necessary to amputate the gangrenous portion of the limb.

95. Overall, 2,485 doctors in 143 counties in Mississippi, Alabama and Georgia which were heavily and moderately

infested by imported fire ants were surveyed during August, September and October 1971. 1,336 or approximately 54 percent of the doctors surveyed, responded. 901, or approximately 67 percent of those responding, reported they had treated patients for imported fire ant stings or complications from such stings. 12,438 patients were treated by these doctors for imported fire ant stings or complications during the first 7 to 9 months of 1971. 6,788 of these patients required treatment for secondary infection. 428 required extensive debridement. 6,182 patients had allergic reactions involving localized swellings. Of these 1,356 had generalized urticaria and/or angioedema. 561 patients had other systemic symptoms. A total of 76 cases of anaphylactic shock was reported for the first 7 to 8 months of 1971 in Mississippi and the first 9 months in Alabama and Georgia. For 1970, 52 cases were reported. For 1969, 27 cases. Seventeen deaths resulting from imported fire ant stings were reported by the doctors surveyed.[11]

CONCLUSIONS

I

As stated by the Administrator in his notice of intent to suspend registrations of pesticides containing heptachlor or chlordane, in effect, instituting this proceeding, dated July 29, 1975, "In accordance with FIFRA section 6(c), where the Administrator finds that 'action is necessary to prevent an imminent hazard during the time required for cancellation . . .' he may by order suspend the registration after providing an opportunity for an expedited hearing on the question of 'whether an imminent hazard exists'. The term 'imminent hazard' is defined by FIFRA section 2(*l*) to mean a 'situation which exists when the continued use

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[11] Although precise numbers are reported, due to an inability to, in part, cross-examine as to these statistics, with respect to Georgia and Alabama, the absolute numbers should be regarded as general indications of results.

of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment . . .' " The phrase "unreasonable adverse effects on the environment" is, in turn, defined by section 2(bb) of the act (7 U.S.C. 136(bb)) to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

In this connection, the Administrator further stated in his notice, as follows:

> The courts have repeatedly "cautioned that the term 'imminent hazard' is not limited to a concept of crisis: 'It is enough if there is *substantial likelihood* that serious harm will be experienced during the year or two required in any realistic projection of the administrative [cancellation] process.' " *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency,* 510 F.2d 1292, 1297 (D.C. Cir. 1975) (emphasis in original), quoting from *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency,* 465 F.2d 528, 540 (D.C. Cir. 1972). Of course, as in the cancellation proceeding, the Administrator does not have the burden of proving that a pesticide is unsafe since the statute and case law place "[t]he burden of establishing the safety of a product requisite for compliance with the labeling requirements . . . at all times on the applicant and registrant." *EDF* v. *EPA,* 510 F.2d at 1297, *EDF* v. *EPA,* 465 F.2d at 540.[12]

[12] Registrant Velsicol Chemical Corporation took the position at the hearing that the language of the Court in Environmental Defense Fund, Inc. v. Environmental Protection Agency, 510 F.2d 1292, 1297 (D.C. Cir. 1975) with respect to burden of proof of safety is merely dicta and that such burden is not placed upon it in this proceeding under section 6(c) of the act. Of course, it is clear that the Administrator so held in his October 1, 1974 opinion in the aldrin/dieldrin suspension proceeding (In re Shell Chemical Company, *et al,* FIFRA Dockets No. 145 et al. (39 F.R. 37265) and we are bound thereby and by section 164.121(q) of the rules of practice (40 CFR 164.121(q)) which so provides. In addition, this registrant's arguments in this regard are lacking in merit, we

In addition, crucial to any description of this proceeding is the holding of the Court in *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency,* 510 F.2d 1292, 1298 (D.C. Cir. 1975), the sole suspension proceeding under section 6(c) of the act, that " 'the function of the suspension decision is to make a preliminary assessment of evidence, and probabilities, not an ultimate resolution of difficult issues. We cannot accept the proposition . . .that the Administrator's findings . . . [are] insufficient because controverted by respectable scientific authority. It [is] enough at this stage that the administrative record contain[s] respectable scientific authority supporting the Administrator.' Environmental Defense Fund, Inc. v. EPA, *supra,* 150 U.S. App. D.C. at 357, 465 F.2d at 537."

II

Much of the initial controversy herein turns on the results of the review of slides of basically the rodent liver by pathologists.[13] Velsicol Chemical Corporation takes the position, in effect, that this is a very subjective matter among pathologists and that this proceeding merely describes differences of opinion among pathologists based on their subjective examination of mouse and rat liver slides and that, therefore, the carcinogenicity of heptachlor and chlordane has not and, perhaps, cannot be established herein. There is some validity to this position. A certain degree of sub-

believe. It would be strange, indeed, that the 1972 amendment to the act would change the cornerstone of the statute without mention. Such amendment to section 6(c) merely related to the status or type of presiding officer that could conduct the proceeding and did not, in reality, address or change the central issue of burden of proof of safety.

[13] This factor distinguishes this proceeding from the aldrin/dieldrin suspension proceeding (In re Shell Chemical Company, FIFRA Dockets No. 145 et al., October 1, 1974, affirmed Environmental Defense Fund, Inc. v. Environmental Protection Agency, 510 F.2d 1292 (D.C. Cir. 1975)) in that in such proceeding it was not, in reality, disputed that those pesticides induced cancer in 5 different strains of mice.

jectivity is involved and it is not expected that there would be complete agreement as to the diagnosis of the classification of a particular lesion found on a particular slide of a rodent liver in all cases. But, it appears to us that some of the divergence demonstrated is, in reality, a matter of semantics or nomenclature rather than substance.

Respondent had Dr. Reuber conduct a reexamination of all or nearly all slides in various experiments where heptachlor, heptachlor epoxide, combinations thereof, or chlordane were administered to mice or rats. Dr. Williams also looked at most of the heptachlor CFN rat slides. Additionally, selected slides from some of these experiments were reviewed by additional pathologists on behalf of respondent, namely, Drs. Stewart, Squire, Williams and Popper. Also, Velsicol sent to pathologists and others slides from some of these experiments. These were Drs. Newberne, Sternberg, Deichman and MacDonald, Becker and Rust. Frankly, we were somewhat startled when we realized the significance of the examination of selected slides by pathologists on behalf of Velsicol in 1972 and in 1974 and 1975.

It should be emphasized at this point that the consultant pathologists utilized by respondent generally confirmed and agreed with Dr. Reuber's classifications and diagnoses [14] and that those employed by Velsicol mentioned above then also did so.[15] It is highly significant, we believe, that none of these pathologists previously consulted by Velsicol, other than Dr. Rust, were called as witnesses by Velsicol. It should further be stated at this point that Dr. Reuber is a well qualified pathologist and expert in the field of the rodent liver and that examination of his

[14] While the record demonstrates some differences in diagnosis of individual slides by experts presented by respondent, such differences are largely a matter of semantics or nomenclature as explained by such witnesses on cross-examination.

[15] Dr. Rust initially, in effect, agreed with Dr. Reuber's diagnoses but disagreed emphatically on a more substantial rereview.

credentials and publications confirms this fact.[16] Also, he was relied upon by the Administrator in the aldrin/dieldrin proceeding. While Dr. Reuber does not make an imposing witness on the stand due to nervousness his qualifications as a pathologist especially in the area of the rodent liver are impressive and, as seen from his diagnoses, when compared with those of others, he cannot be characterized as extremely liberal. His diagnoses were confirmed by the other pathologists presented by respondent and, in reality, by those mentioned above who were selected by Velsicol. It need be stated at this point also that the pathologists utilized by respondent are each well qualified as are those employed by Velsicol and that Drs. Popper and Stewart are especially renowned in the field of liver and liver pathology. In fact, Dr. Rust, a witness for Velsicol, testified that "I think Hans Popper is one of the great men in liver disease, and so is Red Stewart . . . they are two of the greatest."

Time does not permit and no useful purpose would be served by a detailed description and examination of each of the experiments involved. However, we shall briefly discuss some of these studies as illustrative generally of the state of the record with respect to the studies at issue and especially the studies conducted for Velsicol Chemical Corporation by the International Research and Development Corporation and, in part, by Kettering Laboratory.

A 2 year feeding study was conducted by the United States Food and Drug Administration utilizing the C3H mouse fed heptachlor or heptachlor epoxide at 10 parts per million. While there were some shortcomings to this experiment, it was found in 1969 by the Advisory Panel on the Carcinogenicity of Pesticides, Report of the Secret-

[16] Velsicol's attempt to discredit Dr. Reuber on the basis of his analysis of 2 non-liver tissue slides does not detract from his background with respect to rodent livers. Also, the slides in question were made in 1975 and were to some slight degree at least different from the slides reviewed by Dr. Reuber.

ary's Commission [USDHEW] on Pesticides and Their Relationship to Environmental Health that heptachlor was "positive" for tumor induction. Dr. Gross, in this proceeding, statistically analyzing the data from this study found this also to be the case with a great deal more statistical significance. Tumor induction itself has substantial meaning. Dr. Reuber, upon reanalysis found statistically significant increase in carcinomas in the treated animals, which animals developed much larger carcinomas than the few controls with carcinomas, some metastasis in treated animals and treated animals with multiple carcinomas. Slides from 20 animals from the treated group in this study, 19 of which were diagnosed by Reuber as having carcinomas were submitted to Drs. Stewart, Squire and Williams by respondent and to Dr. Sternberg by Velsicol Chemical Corporation. Each of these pathologists, in effect, confirmed Dr. Reuber's diagnoses with Drs. Sternberg and Stewart finding 20 carcinomas.

The Velsicol Chemical Corporation employed the International Research and Development Corporation to conduct a study of CD-1 mice [17] fed a mixture of 75 percent heptachlor epoxide and 25 percent heptachlor for 18 months at dietary levels of 1, 5 and 10 ppm. Included in the experiment were a negative control group and a positive control group fed 250 ppm of 2-acetamidoflourene (2AAF), a known carcinogen. The pathologists who reviewed slides from this experiment disagreed sharply, in effect, with the original analysis thereof. This includes those selected by Velsicol, namely, Drs. MacDonald and Deichman, Drs. Newberne, Becker and Rust,[18] and those utilized by respondent, namely, Drs. Stewart, Squire and Williams. It is significant that each of those consulted by Velsicol diagnosed

[17] This mouse is a hardy, non-inbred strain with a low incidence of spontaneous tumors generally and is used widely as a standard animal for carcinogenicity screening studies.

[18] Dr. Rust's rereview and Dr. Butler's review will be dealt with later herein.

more animals with cancer than was diagnosed by the International Research and Development Corporation in this entire experiment even though they examined slides of relatively few animals. Of even greater significance is Dr. Newberne's report that the majority of the sections examined were "*frank* liver cell carcinomas" which represented malignant change "beyond nodular hyperplasia." (Emphasis supplied.) The record indicates that the word "frank" has great meaning. It is recognized that Dr. Newberne was also seeing a few slides from positive control animals but his diagnosis included carcinomas in treated animals.

The bulk of the slides from this experiment was reviewed by Dr. Reuber and he found a highly statistically significant incidence of hepatocellular carcinomas in male mice at the 5 and 10 ppm level and in female mice at 10 ppm. This was so even though the study may have been weighted toward a negative result due to the fact that animals with liver masses could not be reviewed histologically by reason of their being autolyzed. Basically, the entire situation described above is the same with respect to the IRDC mouse study involving chlordane.

There are further indications in recent studies conducted by Gulf South Research Institute for the National Cancer Institute as to the carcinogenicity of heptachlor and chlordane in the mouse which lend some confirmation to the other studies discussed above. However, only preliminary data is available with respect thereto and we have some serious questions as to the protocols followed therein, that is, with respect to the size of the control group and the dosage fed and do not now rely on these studies pending further examination thereof in the cancellation proceeding involving heptachlor and chlordane.

In reality, there is only one carcinogenicity experiment in point involving the administration of the pesticide hepta-

chlor to the rat. That is the 1959 Kettering Laboratory rat study done for Velsicol Chemical Corporation involving the CFN rat fed dietary levels of heptachlor epoxide at 5 dose levels ranging from 0.5 to 10 ppm. Here again, the Gulf South Research Institute studies done for the National Cancer Institute are only preliminary in nature and contain problems with respect to the size of the control group and the dosage administered.[19]

The Kettering study did find an excess of "hepatomas" in the treated animals but concluded that "The data obtained from these animals are not sufficient to implicate Heptachlor epoxide as the agent responsible for the development of these hepatomas." Here again, however, the Mrak Committee, as was the case with the 1965 FDA mouse study mentioned above, on the basis of statistical analysis, concluded that heptachlor should be classified as a compound "judged to be 'positive' for tumor induction on the basis of tests conducted adequately in one or more species, the results being significant at the 0.01 level." Dr. Gross, a qualified pathologist and statistician, reported several highly statistically significant increases in tumors in female groups and in the males and females combined.[20]

In addition, there was independent evaluation of the liver histology by Drs. Reuber and Williams, and the examination of selected cases by Drs. Stewart, Squire and Popper.

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[19] The studies are partially suggestive of a carcinogenic effect of chlordane and heptachlor in the liver of rats. They do not appear to be as supportive of that conclusion, however, as the preliminary studies with respect to mice and will be considered after fuller exploration with respect thereto in the cancellation proceeding to follow. While there were other rat studies, including one done by Kettering, they are not, in effect, usable as carcinogenicity studies but did not, however, indicate negative results.

[20] We are in agreement with Dr. Gross, and not with Dr. Carlborg, that in safety testing of suspected carcinogens a one-sided test for probability is appropriate.

The number of carcinomas in the liver and elsewhere found was especially significant because of the rarity of this finding and the finding of neoplastic nodules *now, perhaps, takes on added meaning* with respect to the rat. We are especially impressed by the testimony of Dr. Popper, the biological significance he attributed to his findings and his statement that *"I am convinced this is one of the most potent carcinogens of which I can recall . . ."* (Emphasis supplied.)

We are inclined to believe that the record does not contain substantial or meaningful refutation of the results of the FDA heptachlor and heptachlor epoxide mouse experiment reported by Dr. Reuber. With respect to the IRDC mouse experiments, we are faced with a rather strange situation. Velsicol presented the pathologist who performed the original analysis to affirm, in effect, his original report and for sophisticated theories and distinctions, in part, between the positive control and treated animals. Yet, his original diagnosis, in reality, was certainly not affirmed and was in fact contradicted by Drs. Newberne and Becker, Dr. Rust, both in his original examination of the slides and even somewhat on cross-examination at the hearing, and by Drs. Reuber, Squire, Popper, Stewart and Williams. It is also suggested in the record that when the original diagnostician "reviewed the slides back in approximately 1973, the criteria for evaluation was not as severe as it is now." In any event, obviously, we are not well qualified to measure the correctness of the histological examination of rodent liver slides. But, we do have experience in weighing evidence and the credibility thereof. By virtue of the setting in which the testimony of the original diagnostician is presented herein we cannot give his rediagnosis and analysis great weight. We mean no disparity of his professional abilities and are uncomfortable in this connection, but we feel, on the basis of the record, restricted as

to the weight to be accorded to his testimony herein.[21] In addition, such pathologist, who has no great experience or background in experimental pathology and has not studied intensely the development of tumors has made statements in that regard which he was not particularly qualified to make and on the basis of insufficient data.

We are also presented with a rediagnosis of the 1959 CFN rat slides by the pathologist who performed much of the original diagnosis, which diagnosis was greatly weakened, we believe, by the findings of Drs. Reuber, Williams, Stewart, Squire and Popper, whose diagnostic criteria appear to be in agreement with Drs. Newberne and Becker generally. In fact, as indicated above, Dr. Popper concluded on the basis of the selected slides from this experiment which he reviewed that "I am convinced this is one of the most potent carcinogens of which I can recall . . ." and whose diagnosis of individual slides differed from the original analysis. By reason of our conclusions with respect to the reanalysis of IRDC mouse slides by the pathologist who was originally involved with such bioassay and with the same reservations we expressed there, the 1959 CFN rat slide rediagnosis by the pathologist submitted by Velsicol herein cannot be given great weight. In addition, the pathologist involved is not expert in experimental pathology.

We are not unmindful, however, of the testimony of Dr. Butler, an expert in hapatic carcinogenesis in rats and

[21] By reason of these facts and the record as a whole, we feel that these matters should, perhaps, upon return to the heptachlor/chlordane cancellation proceeding, be submitted to the National Academy of Sciences for consideration. Also, while we agree with Velsicol that the opinion of the original investigator is entitled to weight we cannot so evaluate such opinion in this instance. There is a suggestion in the record that the reexamination of slides by experts in experimental pathology is somehow unethical. This record demonstrates a decided need for such reanalysis.

mice, and Dr. Rust. In addition, their testimony tends to confirm and corroborate the testimony of the original diagnosticians employed by IRDC and Kettering and for that reason we have certainly not totally discounted the testimony of the original diagnosticians. It should be stated that Dr. Butler appears to be extremely conservative in the area of the degree of metastasis required and by reason thereof we have some reservations as to his testimony. In addition, some of his testimony is based on speculation, surmise and unproven hypotheses. We cannot rely in this proceeding on some of his general testimony until the state of our knowledge is much more advanced.[22] We recognize that this comment to some lesser extent need be applied to respondent's witnesses. Also, Dr. Rust's change in diagnosis of slides from 1972 to 1975 is disturbing although he presented a somewhat reasonable explanation for such change.

Despite what we have said above, we have great difficulty with the differences in the diagnosis of individual liver slides between Drs. Butler and Rust and Dr. Reuber and others and cannot disregard the histological appraisals of Drs. Butler and Rust or state that they are necessarily in error or employ improper criteria. In reality, we do not feel competent to do so. Added to this is the apparent absence of metastasis or invasion. Dr. Rust looked for metastasis but did not find it.[23] There is some reference to

[22] For example, Dr. Butler himself states that "The diagnosis of benign neoplasia—adenoma—of the liver presents considerable problems and it is recognized that this diagnosis cannot be made in rodent liver at present . . . In the rodent liver, in order to demonstrate a noninvasive lesion to be an adenoma, it would be necessary to demonstrate that the proliferation of cells is automonous. So far, this has not been done, and hence the diagnosis of benign liver cell neoplasm or adenoma is not made."

[23] While metastasis was not found in the IRDC data, many of the animals did not survive and the rest of the animals were sacrificed too early for metastasis to develop perhaps. There were

"microinvasion" in the evidence in connection with Dr. Becker's diagnosis of selected slides but it is unexplained and there is no other significant reference to invasion with respect to the liver slides at issue. But cf. *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F.2d 1155, 1158 (3d Cir. 1974) where "mice under experimental exposure . . . developed tumors with 'malignant potentiality'." See also, however, the working draft of the National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis.

By reason of the foregoing, we conclude that heptachlor and its metabolite *appear to be* a carcinogen in the mouse on the basis of the FDA and IRDC studies and *may be* a carcinogen in the CFN rat [24] on the basis of the Kettering study and that chlordane *appears to be* a carcinogen in the mouse on the basis of the IRDC study involved. We have utilized the phrases "appear to be" and "may be" because we are troubled by the histologic findings of Drs. Butler and Rust to the contrary and the absence of meaningful metastasis or invasion and feel very strongly that these matters should be reviewed by others more qualified with respect to pathology than we for a more definitive appraisal (See footnote 21). In other words, we are *hesitantly unwilling at this time* to find that heptachlor and chlordane are conclusively carcinogens in laboratory animals.[25]

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suggestions or limited findings of metastasis but they do not appear to be significant enough to be meaningful. It should be stated, however, that not much in the way of metastasis was found in connection with the 2AAF treated mice, 2AAF being a known carcinogen.

[24] We recognize, however, that there is some question as to the appropriateness of the CFN rat as a test animal.

[25] The Administrator could perhaps do so on the basis of this record. Should he so conclude, we state briefly for his consideration that the record contains no valid epidemiologic proof that the pesticides at issue are safe with respect to the question of cancer

We are not unmindful in this connection that currently attention is being given "to efforts that better define, in functional terms, a chemical carcinogen, and to the development of general guidelines which can be used for interpreting carcinogenicity data." These efforts have not affected our conclusions set forth above as the results thereof have not been determined. But, it is hoped that assistance can be rendered by the attention focused on this area in the heptachlor/chlordane cancellation proceeding. Also, we do not wish to leave the impression that the safety of heptachlor and chlordane is not still a matter of grave concern. In other words, they are not "home free" by any means with respect to whether they are carcinogens in laboratory animals and a potential carcinogenic risk to man. We merely state that at this time we do not so conclude and, by reason thereof, we cannot find an "imminent hazard" with respect thereto.

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and that Velsicol's position that heptachlor and chlordane are present in our food supply at "virtually safe" levels under the Mantel-Bryan formula and otherwise does not take into consideration other avenues of exposure to the chemicals such as inhalation and dermal contact, does not account for the wide variability in human susceptibility as compared to laboratory animals and different degrees of exposure, considers exposure only to a single carcinogen, has not been established appropriately according to the testimony of Mr. Mantel and Dr. Schneiderman and may not be the test for safety to be utilized according to such witnesses. In reality, the attempt to establish a safe level of a carcinogen for man is in its infancy and we are not, on the basis of this record, at a point where this can be done for heptachlor and chlordane. Cf. Working draft of the National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis. We have serious doubts that mouse data can be quantitatively extrapolated to man in this respect. Also, the Administrator, on the basis of the record, could determine that the pesticides involved pose potential or possible carcinogenic hazard to man basically for the reasons stated in the aldrin/dieldrin suspension proceeding. It should be stated in this connection, however, that the significance of animal laboratory results to man is also a matter of current concern and examination.

III

We have been concerned up to this point with the risk factor involved in the risk-benefit analysis required in this proceeding. Cf. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency, supra.* Our findings in part II of these Conclusions would obviate the necessity for a consideration of the benefit side of the equation. However, should the Administrator disagree with our findings there, as well he might, we hereby present our analysis of the record on the question of benefits.[26] In this connection, it should be stated that heptachlor presents a greater question of risk than chlordane, both in terms of the amount of incriminating evidence in that regard and its presence in our foods generally as compared to chlordane, and that where the use of these 2 pesticides is interchangeable, we only recommend chlordane and not heptachlor. This preference was also that of most benefits witnesses presented by the United States Department of Agriculture and Velsicol, not necessarily for the reasons stated.[27]

Heptachlor and, in particular, chlordane are apparently the last of the widely used persistent chlorinated hydrocarbons which have been utilized in agriculture and other

[26] Also, we fear that otherwise the benefit considerations might be submerged in the consideration of the risks. Due to the nature of the suspension proceeding, the record is not as complete as it might or would otherwise be with respect to benefits in a cancellation proceeding.

[27] By letter dated November 25, 1975, Velsicol Chemical Corporation stated that "As of November 24, Velsicol has voluntarily restricted domestic shipments of heptachlor to use for termites until a decision is reached by the Administrator regarding suspension. Should the Administrator find in favor of the continued use of heptachlor during a cancellation proceeding, Velsicol shall, nevertheless, voluntarily restrict domestic shipments of heptachlor to uses for termites, seed treatment, fire ants and pineapples pending completion of that proceeding." It is unclear, however, whether Velsicol could similarly restrict the end use products of the formulators to which it sells technical heptachlor although it states an intention to do so.

areas for many years. It seems to us that perhaps we may not be at the point where they can be discarded completely even if considered to be a carcinogenic hazard to man. The Administrator has recognized this to some extent in his suspension order, in effect, instituting this proceeding and in the notice of intention to cancel as well by allowing their continued utilization for termite control in a somewhat "closed" system and for the dipping of the tops and roots of nonfood plants. It may well be that after the cancellation proceeding involving these pesticides that, even if the decision is adverse to such pesticides, a period of transition or phase-out might be necessary as to certain limited uses or that certain limited uses would remain. We speculate in this regard because the record in this suspension proceeding demonstrates that certain uses should be continued during a period of suspension when taking into account "the economic, social, and environmental costs and benefits" of these pesticides, as we must. The record is not as complete as we would like it to be on the question of benefits. However, there follows our somewhat abbreviated appraisal thereof, limited by the time allowable for this Recommended Decision and the paucity of the record in certain respects with recognition of the obvious fact that these conclusions may well be altered after the much fuller record expected to be available after the completion of the cancellation proceeding.

Heptachlor Use Should be Continued During a Suspension for— [28]

1. Seed treatment is used to decrease stand loss attributable to seed eating insects and is intended to protect grain and vegetable seed up to the germination period. (See Findings of Fact 53-58). A *minimal* amount of insecticide is utilized *on a per acre basis.* The only recommended alterna-

[28] Obviously, this analysis does not include consideration of the environmental impact of the utilization of heptachlor or chlordane or health risks other than that considered herein.

tives to heptachlor for this purpose are lindane, diazinon or a combination of lindane/diazinon. However, supplies of lindane are scarce and a substantial portion of the heptachlor seed treatment use may not be made up by lindane. Some question exists as to the "safety" of lindane.[29] In addition, diazinon may present some problem as to its ability to protect seed against the wireworm and lack of efficacy and phytotoxicity data prevents an accurate appraisal as to whether diazinon will be a good seed treatment substitute under all conditions. The need for seed treatment is especially severe in the Southwest part of the country and especially on sorghum seed. Severe potential losses are possible in the absence of treated seed in the Southwest. Commercial seed companies do not now treat seed with heptachlor prior to sale. It is applied by the farmer at time of planting by planter-box or drill-box treatment. Chlordane has not been perfected for such use. Of course, this record was not concerned with the environmental consequences of treated seed. The effect thereof upon birds, for example, need be considered in the cancellation proceeding.

2. An extremely minimal amount of heptachlor is utilized to treat against the narcissus bulb fly by the use of heptachlor bulb dips prior to planting. For example, approximately 200 pounds of heptachlor are used for this purpose in the State of Washington, a major production area. Substantially less heptachlor is used in Oregon. This use may come within the Administrator's exception from suspension of the dipping of roots of nonfood plants and, if not, it certainly comes within the spirit thereof. The minor amount used on nonfood plants, the confined nature of such use, the totally unsatisfactory alternative of field treatment with much more pesticide to bulb dips prior to planting and the fact that the use of heptachlor is a short

[29] But see Environmental Defense Fund, Inc. v. Environmental Protection Agency, *supra* at p. 1303 where the Court discusses a somewhat similar situation between aldrin and heptachlor.

range matter as promising alternatives may soon be available all support a conclusion that this use of heptachlor should be continued during the pendency of the cancellation proceeding. Even a potential or possible 3.5 percent injury of total acreage in Washington and Oregon, which was the experience prior to the utilization of heptachlor dips 20 years ago, is unacceptable under the conditions presented. (See Findings of Fact 59-62).

3. The Hawaiian pineapple industry has presented a very striking need for a pesticide to deal with ants having a commensal relationship with the mealybug, which is the principal cause of mealybug wilt, a potentially devastating disease in pineapple fields. (See Findings of Fact 73-79). It seems to us that mirex [30] presents an effective and, perhaps, preferable alternative to heptachlor due to the small amount of chemical utilized although its use is not as flexible as the use of heptachlor by reason of label restrictions, that is, mirex, as a broadcast treatment of pineapple fields, may be applied only once in any 12-month period. Such restriction may, of course, be altered and mirex appears to be the preferred treatment of pineapple growers. However, mirex is the subject of a proceeding under section 6(b)(2) of the act and its continued use is in question although the fact that action was instituted under section 6(b)(2) would indicate less cause for questioning safety as distinguished from a suspension proceeding or a notice of intent to cancel under section 6(b)(1) of the act, the source of the cancellation notice with respect to heptachlor and chlordane.[31]

[30] We know nothing, of course, as to the "safety" of mirex and our discussion in this decision with respect thereto does not and cannot weigh this factor.

[31] Section 6(b) of the act (7 U.S.C. 136d(b)) reads, in part, as follows:

> "(b) Cancellation and Change in Classification.—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes

In any event, because, in part, of the uncertainty as to the status of mirex under the act, the availability of supplies of mirex is questionable. In the absence of mirex, heptachlor need be available for this use and a great amount of heptachlor is not required. Heptachlor is applied in relatively small quantities, within prescribed boundaries, under close, professional supervision and at infrequent intervals. In addition, a zero tolerance exists for residues of heptachlor on raw pineapples (See 40 CFR 180.104). It seems to us that continued heptachlor use indirectly against the mealybug should be allowed during a period of suspension with the *proviso* that should mirex use be continued for this purpose at the conclusion of the proceedings under section 6(b)(2) with respect thereto and the supply of mirex is once again assured, this suspension proceeding could, if deemed appropriate by the Administrator, be held open or reopened to consider the effect of mirex availability on these conclusions.[32] The consequences of the absence of mirex and heptachlor could potentially be very great to an industry which is already hard pressed. It is not certain that mealybug wilt would reoccur in devastating fashion absent chemical control, but the possibility is too real for the risk of no chemical treatment.

Chlordane Use Should Be Continued During A Suspension for—

1. Chlordane is basic and crucial to the Federal-State quarantine programs involving the Japanese beetle and the

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unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

"(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

"(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

[32] This proviso is applicable to each of the uses mentioned herein where mirex is an alternative to heptachlor or chlordane.

imported fire ant (See Findings of Fact 23-30). These are programs authorized by the Congress and the Secretary of Agriculture of the United States and we are not in a position now to measure their worth and perhaps should not do so in any event. These programs clearly require, as a practical matter, the application of a persistent pesticide and could not function, as presently constituted, without the use thereof. Fumigation and dips are not practical under the programs for general use. While mirex is a substitute, in part, with respect to the imported fire ant, it is not so with respect to the treatment of nursery stock and there are problems as to its availability, as indicated above.

2. The State of Michigan has a nursery quarantine program with respect to the black vine weevil and the movement of infested nursery stock, that is, infested Japanese yews. (See Findings of Fact 31-32). It does not appear that a large amount of chlordane is required under this program and there appears to be no substitute therefor. There is no basis in the record to appraise and, in fact, we are not aware of other similar state quarantines which are independent of the Federal quarantine program. (But see footnote 10). Also, there may be some need for chlordane for nursery use against the black vine weevil, but the record is unclear in this connection and we make no such recommendation.

3. Another insect with which we are concerned is the whitefringed beetle. (See Findings of Fact 34-41). Until very recently it was subject to a Federal-State quarantine program. Apparently, there is no chemical substitute to chlordane for use against this insect which is found in the states of Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina and Tennessee, and alternative methods of control, both chemical and nonchemical, are not currently available as a practical matter. We have been unable in this record to determine with any

precision the extent of damage or economic loss that might be expected from this insect absent chlordane. However, it appears that some would occur in peanut acreage and other crops in the southeastern part of the country, that the insecticide is usually utilized when adult beetles are seen in a field, it is incorporated into the soil and it does not appear that large amounts of chlordane are required. We conclude that chlordane should not be suspended for use in the 8 state area listed above against the whitefringed beetle except in the case of tobacco. A witness indicated that diazinon may be utilized in lieu of chlordane in the treatment of tobacco by mixing diazinon with water used in the transplanting of the tobacco plant. It does not appear likely that the whitefringed beetle could or would spread beyond the 8 state area during the period of time necessary to complete the cancellation proceeding.

4. We turn our attention now to the use of chlordane against the Fuller Rose Beetle on citrus in Florida and on other root weevils considered pests of Florida citrus except the West Indian Sugarcane Stalk Borer Weevil for which it is not now registered. (See Findings of Fact 42-50). Some question exists as to whether it is registered against the Fuller Rose Beetle, but that is a matter for the attention of administrative officials. We were extremely impressed by the Florida integrated pest control programs utilized to control much more important citrus pests than those in issue and the effect the application of foliar sprays to control the root weevils could have upon the integrated pest control program.[33] The foliar applications would kill the beneficial parasitic wasps relied upon to control scales and mites, much more serious pests to Florida citrus than the root weevil. Further, the record indicates that large amounts of chlordane are not used, that only a portion of

[33] This was not made apparent in the aldrin/dieldrin suspension proceeding.

affected or potentially affected acreage is treated each year, and that economic impact could result from failure to control the Fuller Rose Beetle in the Indian River area of Florida especially. We realize that the economic impact will not be that severe during a period of suspension, but some economic impact is to be expected. It should be stated, however, that promising substitutes to chlordane are known, but that further research with respect thereto has come to a halt apparently. We believe that such research should continue rapidly.[34] It also appears that chlordane is used against termites in the planting of new citrus trees in Florida. The United States Department of Agriculture reports only a relatively minor loss from termites, the record is not adequate for appraisal of this use and, by reason of the foregoing, we cannot now recommend that such use should be continued pending completion of the cancellation proceeding.

5. The use of preplant soil treatment of chlordane in strawberry beds protect the plants against the feeding of root destroying insect species for several years (See Findings of Fact 69-72). As no crop is produced the first year and as some strawberry growers plan to fruit their beds 4 to 6 years, a preplant persistent soil insecticide may be fairly essential to strawberry production. Soil insects are an especial problem if the land had previously been in sod and, in fact, New York State recommends, for example, the use of chlordane in strawberry production only if the land utilized had previously been in sod. Much of the problem of soil insects in strawberry production can be solved by rotation. But, alternative chemical controls to the use of chlordane are limited and the record indicates that significant national impacts could occur on the production of

[34] California use of chlordane against the argentine ant in citrus also may be helpful on limited acreage to prevent a disruption of their integrated pest management program. However, the record is totally deficient in this regard.

strawberries absent chlordane, as testified by the witness presented by respondent on the issue of economic impact. Other chemicals such as diazinon and carbaryl reportedly are effective controls but are not registered at sufficiently high rates of application to provide effective control. While fumigation is utilized in California, the practicality of its use elsewhere, especially in the Northeast, has not been established.

6. The harvester ant is often present in large numbers in the more arid areas of the Western United States and may become a health problem. (See Findings of Fact 89-91). The record only indicates the need for chlordane bait against the Texas harvester ant or Pogonomyrmex barbatus in the State of Oklahoma and its use therefor in that form in this State should be continued. Here again, mirex bait might be an alternative. The witness presented by Velsicol with respect to the harvester ant indicated that different ecological conditions exist in other states, and that, therefore, the state recommendations in such other states for chemical treatment against such ants are not applicable to Oklahoma. For these reasons chlordane bait application is recommended to be continued in Oklahoma and the use of such pesticide is not recommended herein for use elsewhere against the harvester ant.[35]

7. The imported fire ant presents both a nuisance and health problem in the southern states and it seems apparent that some chemical treatment should be available against

[35] We do not at this time recommend the continued use of chlordane against ticks and chiggers. The testimony in that connection dealt basically with the State of Arkansas. The record indicates that chlordane is not recommended in that State for many uses against these pests, that many insecticides are recommended instead, and that alternates to chlordane exists for those limited uses for which chlordane is recommended. (See Findings of Fact 85-88). In reality, the use of chlordane in recreational areas is all that is involved and diazinon and rabon are adequate substitutes during a period of suspension.

this pest. (See Findings of Fact 92-95). We are presented again with the question of the status under the act, and the availability of, mirex in this connection. Such pesticide in bait form appears to be an effective and, perhaps, an environmentally preferable insecticide against the imported fire ant to chlordane. The only disadvantage stated in the record to mirex bait is the alleged fact that it is slower acting than chlordane. But, in reality, it is not slow in destroying imported fire ant colonies taking about 10 days to 2 weeks. However, as noted above, its availability at present is in doubt. By reason thereof, and *only* by reason thereof, chlordane should be available for use against the imported fire ant. The United States Department of Agriculture has indicated on the record that it has no plans to employ chlordane, in the absence of mirex, in the Federal-State Cooperative Imported Fire Ant Control Program which may again be operative with mirex. Therefore, permitting the continued use of chlordane against the imported fire ant should not result in an extensive increase in the use of chlordane for this purpose. As stated above with respect to the use of heptachlor in pineapple fields, this proceeding could be held open or reopened should mirex once again become available for use against the imported fire ant.

8. The United States Department of Agriculture presented a witness with respect to the problem of white grubs in the State of Michigan and particularly in the heavier soils in the southern half of the Lower Peninsula. (See Findings of Fact 63-68). The problem appears to be especially severe in fields recently removed from sod or heavy weeds. While rotation is in good measure an answer to the grub problem in Michigan, the alternative to chemical control of clean fallow of the land for one year following breaking it from sod does not appear to be an economically viable or practical alternative. Treatments are not recommended unless the grubs are actually found in the field, the

acreage involved is relatively small and, consequently the amount of chlordane to be used is not relatively great, and the economic impact on a limited number of farmers could be significant. We were especially impressed by the fact that the United States Department of Agriculture has singled out this use for special concern. However, in the brief filed and at oral argument the United States Department of Agriculture would expand the testimony of the witness presented to encompass the use of chlordane against the white grub on small grains generally, that is, apparently on a national basis. The testimony included soy beans and dry beans in addition to small grains and was, in reality, limited to Michigan. In addition, the record contains reports of resistance of white grubs to chlordane in other states and fumigation may be a practical alternative elsewhere. The issue of the continuance of this use in Michigan during a period of suspension is very close and we have no basis to extend this use beyond this State and, in fact, might well conclude otherwise depending on the acreage that might be encompassed and the amount of chlordane that might involve. By reason of the foregoing, we recommend that chlordane use against the white grub in the State of Michigan be continued during a period of suspension.[36]

IV

The record indicates that there exist many alternatives to chlordane for use against non-wood destroying household insects.[37] This is recognized, in reality, by the National

[36] Should the Administrator determine to suspend some but not all uses of the pesticides involved, it appears to us that, as a technical matter, a registration containing a suspended and a non-suspended use would need be suspended with the registrant applying for an amended registration conforming to the Administrator's decision.

[37] While the specialized use of chlordane in a shelf paper marketed by Athena Corporation may not be duplicated except with

Pest Control Association, Inc. for professional use and the situation is the same for insecticidal application by homeowners or householders. Similarly, the record further indicates that diazinon and dursban will control soil insects attacking lawns and turf during the period it will take to complete the cancellation proceeding involving chlordane and heptachlor. The efficaciousness of the substitutes for control of household and lawn insects is not really in issue. General arguments are made with respect to the toxicity thereof as compared to chlordane, and the persistence and cost of the alternatives. The registrants have attempted to paint with a very broad brush in this connection. The record indicates that some of the substitutes, in terms of acute toxicity, are less toxic than, some are as toxic as, and some are more toxic than, chlordane. In addition, costs are more or less comparable for the limited period under consideration. It may be that an additional application may be necessary subsequent to the period of our concern, but generally speaking additional applications for lawn protection will not be necessary during the period until the cancellation proceeding is expected to be completed. In any event, we have previously stated and iterate that alternatives to the pesticide or pesticides at issue need not be as efficacious as, and no more costly than, the chemicals at issue when the risk at hand is as ominous as cancer.

We turn our attention to the wood destroying insects other than termites, that is, basically the carpenter ant and the group of insects categorized herein as the powder post beetle (See Findings of Fact 80-84). The record indicates that substitutes exist for treatment against these wood destroying insects. Lindane and pentachlorophenol are registered and recommended substitutes for chlordane against

lindane which is in short supply, many other insecticides are available against household insects by other means of application. It should be mentioned, perhaps, as well that the German roach, which is the predominant roach, is resistant generally to chlordane.

the powder post beetle. Lindane appears to be in short supply and pentachlorophenol has a disadvantage by virtue of its objectionable odor. However, there are also complaints as to odor with respect to the application of chlordane when utilized in an oil based formulation and most or many of the applications would be under the affected buildings. Also, the pest control witnesses who testified in this proceeding indicated that where heavy infestations occur fumigation is necessary and that, in reality, neither chlordane nor its substitutes would be utilized. There also exist substitutes for control of the carpenter ant although we do have some reservation as to whether they are equally effective. As noted above, precise equality of effectiveness should not be an essential element in the risk-benefit equation when the risk in issue is cancer. It should be stated at this point that the suspension of chlordane use against the wood destroying insects would cause some disruption and dislocation in the pest control industry. However, we believe that this is only a transitional problem that can be overcome. We also have some reservations with respect to pentachlorophenol and suggest the Administrator closely reexamine this issue. Should the Administrator disagree with the foregoing analysis, it is suggested that chlordane use against the carpenter ant and powder post beetle be permitted by professional pest control operators only during a period of suspension.

The single most difficult issue in the risk-benefit analysis is the use of chlordane or heptachlor for control of the cutworm in corn production.[38] We are especially concerned in this connection because *millions of pounds* of technical heptachlor and chlordane are involved in this use, and the importance of the 1976 corn crop is self-evident. This repre-

[38] Velsicol has not and, in reality, cannot argue for the use of the pesticides against the corn rootworm by reason of resistance and adequate substitutes are available for use against the wireworm, the wireworm problem to a large extent is a matter of rotation, and there exists some question of resistance.

sents the major use of heptachlor and the major agricultural use of chlordane. Velsicol's commitment not to utilize heptachlor for this purpose may reduce its availability during the pendency of the cancellation proceeding to some extent, but it appears that chlordane production is capable of replacing any heptachlor eliminated by the offer or commitment (See footnote 27).

It is extremely difficult to estimate the effect of a suspension of the pesticides involved upon corn production and, especially, damage to be expected from cutworms. Cf. extensive discussion with respect to the 1975 corn crop absent aldrin in *In re Shell Chemical Company*, I.F. & R. Dockets No. 145 et al., October 1, 1974, affirmed, *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency, supra*, at 39 F.R. 37246, 37260-37262.[39] While corn is the major agricultural use of chlordane and heptachlor, the importance of these two compounds to corn production must be placed in proper perspective. (See Findings of Fact 19-22.) Chlordane and heptachlor together were used on about 2.6 million acres or 3.5 percent of the total corn acreage in the United States in 1975. Chlordane was used on about 1.2 million acres of corn equalling 1.6 percent of U.S. corn acreage. Heptachlor was used on 1.4 million acres of corn equalling 1.9 percent of U.S. corn acreage in 1975. The acres treated with chlordane and heptachlor represent an increase from the average of the years 1973-1974 when only 2.5 percent of corn acres were treated with these compounds. This increase is accounted for in part by the suspension of aldrin in 1974 which led to a decline in the use of aldrin from 9.6 percent of U.S. commercial corn acreage in the average of the years 1973-1974 to 3.3 percent in 1975. The total percentage of corn acres treated with

[39] The Court in Environmental Defense Fund, Inc. v. Environmental Protection Agency, *supra*, at p. 1304 held that the Recommended Decision therein, in effect, was adopted by the Administrator in his Decision except where a difference in commentary is made explicit.

chlorinated hydrocarbons in 1975 was only 6.8 percent of the national total and 8.6 percent of the corn acreage in the 8-state region known as the Corn Belt [40] was so treated, with much of that treatment for "insurance" purposes. Missouri led the nation in percent of corn acres treated with chlorinated hydrocarbons in 1975, treating an estimated 30 percent of commercial corn acreage. The next ranking state, Indiana, was far behind with 14.1 percent.

In reality, projections of loss absent chlordane and heptachlor presented by Velsicol are based upon the estimates of 2 entomologists, which estimates were admittedly "shaky," and are estimates which were not corroborated by other entomologists in the Midwest and, in fact, were disputed by such other entomologists.[41] In addition, the 1975 corn crop is "forecast at a record 5,804 million bushels as of November 1." This was accomplished with the use of considerably less chlorinated hydrocarbon insecticides on corn than had previously been the case by virtue of the suspension and cancellation of aldrin. In fact, the average of the 2 years 1973-1974 indicates that chlorinated hydrocarbons had been used on 12.1 percent of U.S. commercial corn acreage while in 1975 such pesticides were applied on only 6.8 percent thereof. It is recognized that more

[40] The major corn growing states in the United States include Illinois, Indiana, Ohio, Wisconsin, Iowa, Minnesota, Missouri, and Nebraska.

[41] In this connection, Velsicol Chemical Corporation presented a witness who, in part and in effect, reported someone else's analysis of the economic impact of the absence of heptachlor and chlordane for use on corn. We have rarely, if ever, in our experience of presiding at hearings or examining transcripts for the purpose of preparing final decisions witnessed such a presentation. It consisted of misstatements, omissions of known material contradictory to such testimony, slanted presentation of facts, etc. One need only compare the cross-examination to the written direct testimony in this regard so to conclude. Needless to say, we place little reliance or credence upon this analysis with respect to corn.

acreage was devoted to corn production in 1975 and that corn yields were down in certain states. But, the weather, that is, a very dry July and August, probably accounts for decreased yields as compared to 1973 [42] and not cutworm damage. We would have expected in this record detailed and specific evidence as to cutworm damage in the Corn Belt *at significant economic levels* if such injury caused significant yield losses. Such evidence was not, in reality, forthcoming. While an entomologist testified with respect to increased reports of cutworm damage in Ohio, yields are up in that state as compared to 1973 even though there was also some adverse weather experienced there. We cannot similarly appraise the Missouri, Iowa, and Nebraska situation due to severe adverse weather conditions there.

Nor can we determine the amount of corn that might be lost due to cutworm injury and the absence of heptachlor and chlordane. It does appear, however, that the estimates of the 2 entomologists presented by Velsicol are much too high and that the "Delvo estimates" involved in the record also appear to be too high although they are *much* lower than projected by Velsicol's entomology witnesses, especially in view of the opinions of other entomologists in the Corn Belt and other evidence of record. In this connection, it should be stated that the States of Illinois and Iowa do not recommend the use of heptachlor or chlordane for control of the cutworm, confirming, perhaps, the view of some entomologists as to the seriousness of the problem and the availability of substitute treatment. It would be unfair, however, to neglect to state that many corn farmers in those 2 states do not follow the state recommendations in this regard. It need also be kept in mind that the Administrator has indicated in his notice of intent to suspend that

[42] The year 1974 was atypical and yields were low due to unusually adverse weather conditions. A bumper crop was experienced, we believe, in 1973.

existing stocks of these pesticides as of the date of such notice, July 29, 1975, could be utilized. We have been unable to determine the extent of such stocks, but there is some intimation in the record that they could be substantial if the experience with respect to existing stocks of aldrin is typical. In this connection, a nursery witness testified that his large commercial nursery had on hand a one-year supply of chlordane. Some corn farmers may similarly be so supplied. Also, Velsicol has been manufacturing these insecticides during this suspension proceeding and undoubtedly additional supplies thereof are at the dealer and farm level.[43] Further, estimates presented by Velsicol of corn loss have been bottomed basically on the premise that there are no effective substitute chemicals. Such is not the case. In short, we do not believe that Velsicol has established any macroeconomic effect from the suspension of the pesticides involved in relation to corn production.

This is confirmed or corroborated by a linear program model employed by respondent. We have greater faith in, and place greater reliance on, the "September" computer run of the model as the earlier run was based on the "Delvo estimates" of loss which appear, on the basis of this record, overstated. In addition, even the earlier run projects only a 0.7 percent reduction of corn production absent chlordane or heptachlor. This need be modified downward as some existing supplies will be available and utilized in the production of the 1976 corn crop.[44]

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[43] This is a matter the Administrator need consider in connection with his intention to allow the use of stocks existing as of July 29, 1975. We know nothing with respect to the administrative capabilities of following pesticides from the manufacturer or formulator and the record is silent in this regard.

[44] The model was subjected to much criticism. However, it seems to be in line with other evidence of record, some of the criticism was made without real knowledge of the data built into the model or used in the flexibility penalties employed therein and the witness voicing the criticism demonstrated extreme bias in other portions of his testimony although we place greater credence in his testimony with respect to the model than other portions of his testimony. (See footnote 41).

We are concerned about, however, and have *agonized* over the possible effect of such a suspension upon certain individual farmers. The problems presented by a suspension to the corn farmer of Missouri bottomland, for example, are substantial. Again, we are presented with the application of millions of pounds of the pesticides involved and know of no way to define limitations on use to cover only very essential cases since much of the applications of heptachlor and chlordane are for "insurance" purposes with no certainty that a cutworm infestation or an economically significant cutworm infestation will occur.

The cutworm presents a very real threat in certain limited areas in the Corn Belt. The cutworm is associated generally with poorly drained river bottom land, heavy soils and low wet spots in upland fields. There are fields that have a history of cutworm problems. Most farmers, even in Missouri where the problem appears to be the most acute, however, treat in a band or row application which, unlike a broadcast application at a higher rate of the pesticide, does not give protection against and is not effective against a heavy cutworm infestation. This fact need be balanced against the effectiveness of substitute treatment for the cutworm. Additionally, cutworm injury does not generally result in a total economic loss. Injury may not be at economic levels, may be spotty in a field or, if at significant levels, the farmer replants. In the latter event, the farmer suffers the costs of replanting and some loss of yield due to the later planting. But, the individual farmer would not necessarily suffer a net loss for his entire crop or even on affected fields due to the price of corn and the fact that all of his fields need not be affected.

We do not wish to leave the impression that the corn farmer is without any pesticidal protection against the

cutworm absent chlordane and heptachlor. First, diazinon is registered as a preplant treatment against the cutworm. Such treatment does not appear, however, to give total or extended protection and there is some question of its availability in this formulation. In addition, post emergent treatment by baits and sprays are available and, as indicated above, are recommended by the States of Iowa and Illinois as the sole treatment against the cutworm and are recommended by other states in the Corn Belt for emergency treatment, that is, if no preplant treatment was done or if such preplant treatment with heptachlor or chlordane has failed. Also as indicated above, band or row treatment by these chemicals will not control heavy cutworm infestations. In addition, there is some evidence in the record questioning the efficacy of chlordane and heptachlor under other conditions.

The record herein also indicates that post emergent treatment with baits and sprays is effective against the cutworm if infestations are discovered timely and the baits and sprays are timely applied. This requires scouting of suspect fields or parts of fields in order to discover cutworm damage early. Witnesses for Velsicol testified as to why a scouting program cannot be effective for the 1976 corn crop. We agree that a total corn pest management program with trained scouts is not foreseeable for 1976, although the State of Illinois apparently has a successful pilot program. We further agree with the entomologist witnesses for Velsicol that to require the farmer to scout his fields, or have scouts, etc., would represent *a major change* in approach to the cutworm problem and would place an onerous burden upon some farmers at their busy time of year.[45] But, the alternative to this approach is the

[45] As stated in Environmental Defense Fund, Inc. v. Environmental Protection Agency, *supra*, at p. 1302, however, "When the subject is risk of cancer, convenience may be relevant but it does not weigh heavy in the scales."

input into the environment and in connection with a food crop basic to meat and poultry production of millions of pounds of heptachlor and chlordane, assuming for the purpose of this discussion that they represent a carcinogenic hazard to men. It appears to us that the price to society would be too great and that the statute requires otherwise. We do not suggest that scouting by some farmers or their employees will operate as well as a corn pest management program with trained scouts. We do suggest that scouting will provide perhaps somewhat less effective control, but control nevertheless. The situation with which we are presented cannot wait for "perfection." It seems strange, indeed, that the major entomology witness for Velsicol demonstrated extreme reluctance or hesitation to utilize post emergent treatment if suspect cutworm leaf feeding occurs because of uncertainty as to whether such damage was, in fact, caused by the cutworm when he strongly urged preplant "insurance" treatments of heptachlor and chlordane when there exists no evidence of the cutworm's presence at all. In other words, he would demand a degree of certainty for post emergent treatment which does not exist with respect to preplant application of the chemicals at issue. In addition, the States of Illinois and Iowa recognize the effectiveness of post emergent baits and sprays absent a total corn pest management program with trained scouts as do the other states with their recommendations of post emergent sprays and baits as emergency treatment. In addition, if the post emergent alternative is not acceptable to some farmers of bottom land, they have the option, perhaps, of planting other feed crops during the 1976 season.

Some of the reasons advanced for the inability of post emergent treatment to be effective in 1976 are premised on a static situation unresponsive to this decision. We cannot so assume and there is evidence in the record that such is not necessarily the case. We believe that post emergent treatment is a viable alternative even in 1976, but we would be less than candid if we did not state that we have a

"nagging fear" that affected corn farmers may not be willing to adjust thereto. In addition, there is some testimony in the record of a buildup in cutworm populations, but this is not apparently the view of all entomologists in the Corn Belt.

Nor do we find any additional uses of heptachlor or chlordane which should be continued during any period of suspension. The record is too general, imprecise and inadequate and the evidence is too conflicting and uncertain as to other uses to enable us to form a judgment in this regard. For example, there are broad statements with respect to chlordane use on fruits and vegetables generally and the inappropriateness of registered substitutes therefor. The difficult determinations required in a suspension proceeding cannot be made on the basis of such testimony. The delicate risk-benefit analysis is impossible in this context. In addition, we place little credence in the economic analysis presented by Velsicol as to other uses (See footnote 41).

V

Velsicol Chemical Corporation ascribes numerous invalidities to the notice of intent to suspend and the clarification issued in connection therewith. It is difficult, if not impossible, to anticipate all of the arguments to be advanced in this regard. Due to the very short statutory period of time available for the preparation of this decision, its preparation had to begin prior to the filing of briefs or even the closing of the record. Consequently, this decision is responsive to what we had believed Velsicol's position to be and also to what it now is in this connection and also with respect to the substantive issues herein.

On November 18, 1974, the Administrator issued a notice of intent to cancel the registrations of pesticide products containing heptachlor or chlordane (39 F.R. 41298) pursuant to section 6(b) of the statute. Such notice was accom-

panied by a detailed statement of reasons in support thereof. Prior to the beginning of hearings in the consolidated cancellation proceedings, the Administrator, on July 29, 1975, issued his notice of intent to suspend these pesticides. Such notice contained detailed findings of imminent hazard posed by heptachlor and chlordane, as required by the statute. One need only compare the 2 notices to determine the reasons why the Administrator determined to institute the suspension proceeding. The Administrator could have issued his notice of intent to suspend on the basis of an extensive re-evaluation of existing information "which perhaps brought its full impact to the attention of the experts for the first time." *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966). He appears to have issued such notice on the basis of additional laboratory animal carcinogenicity experiments, then recently obtained reviews thereof by consultants for Velsicol Chemical Corporation and the Environmental Protection Agency and additional monitoring data. It is clear that different and additional data were available to the Administrator in reaching his determination to issue his notice of intention to suspend. Also, it is patent that his findings of imminent hazard were adequate to support the notice issued and, in fact, perhaps require its issuance. Cf. *Velsicol Chemical Corporation* v. *Train,* Civil C-75-362 (W.D. Tenn. 1975). The notice of intention to suspend is similar to that issued in the aldrin/dieldrin suspension proceeding which was held adequate by the Court. *Environmental Defense Fund Inc.* v. *Environmental Protection Agency, supra,* at pp. 1299-1300.

Velsicol Chemical Corporation makes much of language in the notice of intention to suspend to suggest that the Administrator has prejudged this controversy. This argument did not impress the Court in an action by Velsicol to enjoin this proceeding *(Velsicol Chemical Corporation* v. *Train, supra)* and does not impress us. After reciting his findings of imminent hazard and at the end of the notice except for a matter dealing with the invocation of section

15(b)(2) of the act in connection with the use of existing stocks of the pesticides, the Administrator stated, in part, that "Although we cannot determine precisely the magnitude of the human cancer risk as a result of the past and continuing exposure to heptachlor and chlordane, I have found that these compounds cause cancer in laboratory animals and that laboratory tests are reliable indications of the human cancer hazard."

The notice of intent to suspend is, in reality, comparable to a conventional complaint instituting an administrative proceeding. It seems to us that the quoted language was comparable to the end of a complaint wherein the issuing authority indicates the consequences of the facts previously alleged or pleaded or the conclusions charged as a result thereof. To ascribe a prejudgment by the Administrator by virtue thereof is, indeed, stretching reason and technical in the extreme. An inference of prejudgment cannot be made on the basis of such language in the context in which it is employed. Cf. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency, supra,* at pp. 1305-1306.

We next turn to an additional portion of the notice of intent to suspend and the clarification issued August 6, 1975. In the July 29, 1975 notice the Administrator stated, in part, as follows:

> As I have repeatedly stated,[4] after extensive EPA experience in evaluating the cancer hazard of pesti-

[4] *See* Opinion of the Administrator, Environmental Protection Agency, on the Suspension of Aldrin-Dieldrin, 39 Fed. Reg. 37265 (October 18, 1974); State of Louisiana Request for Emergency Use of DDT on Cotton, Statement of Reasons for Denial and Supplemental Statement of Reasons for Denial, 40 Fed. Reg. 1934, 15949 (April 8, 1975); Preamble to Subpart A—Registration, Reregistration and Classification Procedures, 40 Fed. Reg. 28242, 28253 (July 3, 1975).

> cides, we do not begin our evaluation of the cancer threat of heptachlor/chlordane in a vacuum. In my prior orders relating to DDT and Aldrin/Dieldren, and in the Preamble to the FIFRA registration regulations, I have set forth the basis for evaluating the carcinogenicity of pesticides which I am applying in evaluating the cancer hazard posed by the use of heptachlor and chlordane for purposes of this suspension notice and which shall be applied to evaluate that hazard in an expedited suspension hearing, if a hearing is requested.

Velsicol Chemical Corporation in its objections to the notice of intent to suspend asserted that such notice was defective in that "the Administrator (a) directs that certain scientific standards be applied and permits no evidentiary challenge to their validity . . ." Velsicol similarly in its court action to enjoin this proceeding complained of this section of the notice as a denial of procedural due process.

On August 6, 1975, the Deputy Administrator, who was apparently the Acting Administrator that day, issued in this proceeding a document entitled "Clarification of Evidence Which May Be Introduced in the Hearing On Suspension of Registrations of Pesticides Containing Heptachlor or Chlordane" in which he stated as follows:

> . . . some uncertainty has arisen with respect to whether registrants or other parties to the hearing are permitted to introduce evidence in challenge to the basis for evaluating the carcinogenicity of pesticides which was referred to in the Administrator's July 29 Notice of Intent. The Notice of Intent set forth the basis for that evaluation and pointed out that such basis was applied "in evaluating the cancer hazard posed by the use of heptachlor and chlordane for purposes of [the] suspension notice and which shall be

applied to evaluate that hazard in an expedited suspension hearing. . . ."

That statement was not intended to foreclose registrants or other parties from introducing evidence in challenge to the basis for evaluation. Rather, it was intended to make it clear that in satisfying its burden of going forward to present an affirmative case in accordance with 40 CFR § 164.80(b), the proponent of suspension is not required to present evidence to establish the points referred to as the basis for evaluating carcinogenicity. In satisfying its ultimate burden of persuasion, however, in accordance with 40 CFR § 164.80(b), the proponent of registration shall have the right to submit relevant evidence in challenge to those points, subject, of course, to rebuttal opportunity by the proponent of suspension.

> The purpose of these rulings was to simplify and expedite the hearing process while preserving a full opportunity for a hearing on all material issues.

It appears to us that in the issuance of the July 29, 1975 notice of intent to suspend the mechanics of the hearing itself were, in part, overlooked, which is not unusual or surprising. In response to the objections raised by Velsicol both in the court proceeding and in the suspension proceeding with respect to its inability to challenge with evidence the scientific standards stated in the notice and the denial of due process alleged to result therefrom, the clarification of August 6, 1975 was issued. In fact, it was issued on the first day of the prehearing conference herein and must have been in process prior to such conference. It's issuance resulted from *ex parte* contact between the Deputy Administrator and the Office of General Counsel.

Velsicol makes much of such *ex parte* contact. We found and find no violation by reason thereof of section 164.7 of the rules of practice (40 CFR 164.7) which provides, in

part, that "At no stage of a proceeding shall the Administrator . . . discuss *ex parte* the merits of the proceeding with any party . . ." The clarification issued by the Deputy Administrator was merely procedural in nature and did not involve the merits of the controversy. In addition, in the court action to enjoin this proceeding Velsicol argued that the notice of intent to suspend [46] and the clarification were tainted by *ex parte* contacts and the court found that the notice and clarification "comply with the Act." The status of the record did not warrant an evidentiary hearing on the question of *ex parte* contacts. The cases cited by Velsicol are clearly distinguishable from this proceeding. Cf. *Camero* v. *United States,* 345 F.2d 798 (Ct. Cl. 1965); *Sangamon Valley Television Corp.* v. *United States,* 269 F.2d 221 (D.C. Cir. 1959). It should be stated at this point, perhaps, that Velsicol's position is somewhat strange in this regard as the clarification issued by the Deputy Administrator clearly afforded it a right which it contended it was entitled to and was being deprived of. The peculiarity is further emphasized by the fact that Velsicol wanted the clarification, which afforded it the opportunity it claimed it was being deprived of, stricken from this proceeding.

In the notice of intent to suspend, as indicated above, the Administrator set forth the bases for evaluating the carcinogenicity of pesticides, which bases those defending the continued use of the pesticides could rebut by evidence introduced in this proceeding. Such bases, as stated by the Administrator culminated from "extensive EPA experience in evaluating the cancer hazard of pesticides" and are found in the totally amended registration, reregistration and classification regulations promulgated under the

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[46] With respect to Velsicol's contentions in connection with *ex parte* contact and the issuance of the notice of intent to suspend see Environmental Defense Fund, Inc. v. Environmental Protection Agency, *supra,* at pp. 1304-1305.

act. In fact, the preamble to such regulations and specifically the discussion with respect to Screening Criteria for Rebuttable Presumption (40 F.R. 28242, 28263) closely parallel the bases stated by the Administrator in the notice of intent to suspend. The chemical industry including Velsicol Chemical Corporation had an opportunity for input into these regulations. Cf. *e.g., Synthetic Organic Chemical Manufacturers Association* v. *Brennan, supra.* It seems strange and wasteful, especially in a suspension proceeding where time is of the essence to engage in a "full dress" reexamination of agency policy. Velsicol availed itself of the opportunity to rebut agency policy.

Velsicol Chemical Corporation sees some sort of plan or ploy in the institution of the suspension proceeding to deprive it of alleged rights it would have in the cancellation proceeding. We know of no such plot. As noted above, the notice of intent to suspend was issued on the basis of additional matters some of which Velsicol apparently did not timely call to the attention of the Administrator as it was its statutory duty to do. We cannot say that the Administrator was arbitrary in the issuance of such notice on the basis of the matters therein contained and, in fact, it appears to us that such matters may well have required the Administrator, with his continuing duty to monitor the safety of pesticides, to issue such notice. The question of the possible suspension of heptachlor and perhaps chlordane is not new and was not created or manufactured for the purpose apparently ascribed by Velsicol. It was a very real issue during the aldrin/dieldrin cancellation and suspension proceedings and even before the issuance of the notice of intent to cancel heptachlor and chlordane. See *In re Shell Chemical Company, et al.,* FIFRA Dockets No. 145 *et al.,* affirmed *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency, supra.*

We have utilized the phrase "alleged rights" in the preceding paragraph to refer to the provisions of section

6(d) of the act dealing with the procedure for the referral of scientific questions to a committee of the National Academy of Sciences. Velsicol appears to see a plot to deprive it of a referral of questions to such a committee. It should be made very clear, as was done on the record of this proceeding, that such referral is not a matter of right and that we had not decided, and certainly had not decided in the affirmative, Velsicol's motion for such referral in the cancellation proceeding when the suspension proceeding was instituted. While Velsicol agrees that there is no provision for a similar submission in a suspension proceeding, the United States Department of Agriculture filed such a request in the suspension proceeding. Such motion was denied as it is patent that section 6(d) dealing with cancellation proceedings does not apply to this suspension proceeding under section 6(c) of the statute. In fact, this is so clear that the filing of the motion in that connection leads one to wonder why it was filed and why it was pursued to the Administrator even though the rules of practice clearly do not provide for such procedure.

ORDER

By reason of the foregoing, the notice of intention to suspend is dismissed.

/s/ HERBERT L. PERLMAN
Herbert L. Perlman
Chief Administrative Law Judge

December 12, 1975

APPENDIX E

UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

FIFRA Docket No. 384

In re

VELSICOL CHEMICAL CORPORATION, *et al.*, Registrants.

(Expedited Hearing On Heptachlor-Chlordane)

Decision of the Administrator on the Suspension of Heptachlor-Chlordane

This is a proceeding under section 6(c)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"),[1] to suspend the registrations of the pesticides heptachlor and chlordane pending a final decision on the question of whether to cancel these registrations. As set forth in this decision and Order, I have concluded that the registrations of heptachlor and chlordane should be and are hereby suspended for some, but not all uses.

I. BACKGROUND

A. *History of the Proceeding*

On November 18, 1974, I issued a notice of intent to cancel all registered uses of heptachlor and chlordane on the basis of a finding that there was a substantial question

[1] The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 135 *et seq.*, as amended by P.L. 92-516, 86 Stat. 973, October 21, 1972. The regulatory authority under FIFRA was transferred from the U.S. Department of Agriculture to the U.S. Environmental Protection Agency by Reorganization Plan No. 3, 1970.

of the safety of the use of these pesticides.[2] The basis of the decision to initiate cancellation proceedings was evidence that heptachlor epoxide and oxychlordane (metabolites of heptachlor and chlordane) were widely found in human adipose tissue, that heptachlor epoxide is transferred from human mothers to their fetuses across the placenta and was present in human milk, that heptachlor epoxide is commonly found in dairy, meat, fish, and poultry in the human diet, that heptachlor and heptachlor epoxide had caused cancer in laboratory animals, and that, in general, heptachlor and chlordane are highly persistent, mobile in the environment, and soluble in lipids.

On July 29, 1975, prior to the commencement of hearings in the cancellation proceeding (discovery and other pretrial activities had begun), because of the time it was taking for the cancellation proceeding to begin and the fact that new evidence which "confirms and heightens the human cancer hazard" of heptachlor and chlordane had come to my attention, I issued a notice of intent "to suspend the registrations and prohibit the production for use of all pesticides containing heptachlor or chlordane other than those registrations exempted from the heptachlor/chlordane cancellation order."[3] Subsequently, on August

[2] 39 F.R. 41298. The cancellation notice specifically exempts "the use of heptachlor and chlordane through subsurface ground insertion for termite control and the dipping of roots or tops of non-food plants." Following the publication of the cancellation notice (and a companion publication regarding intrastate pesticide products containing heptachlor and chlordane, 39 F.R. 41256), Velsicol Chemical Corporation (the sole manufacturer of technical grade heptachlor and chlordane) and many other registrants filed objections to such notice. These objections, together with objections to the notice regarding intrastate products, were consolidated for hearing (*In re Velsicol Chemical Corporation et al.*, FIFRA Dockets No. 336 et al.)

[3] 40 F.R. 34456. Section 6(c)(1) of FIFRA provides that, "No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide."

6, 1975, a clarifying order regarding the introduction of evidence relating to the so-called "cancer principles" was entered.[4]

Under the expedited hearing procedures created by the FIFRA, EPA's implementing regulations,[5] and the July 29 notice, prehearing conferences were held on August 6, 7, and 11, with Chief Administrative Law Judge Herbert L. Perlman presiding,[6] and the hearing began on August 12. By order dated August 6, 1975, Judge Perlman declared the consolidated cancellation proceeding in abeyance pending the outcome of the suspension proceeding.[7]

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[4] "Clarification of Evidence Which May Be Introduced in the Hearing On Suspension of Registrations of Pesticides Containing Heptachlor or Chlordane", 40 F.R. 34455.

[5] 40 C.F.R. 164.120-122.

[6] Judge Perlman was appointed Presiding Officer in the suspension proceeding on August 4, 1975. Thereafter, during the course of the suspension hearing, Velsicol Chemical Corporation petitioned the Administrator to have Judge Perlman removed as presiding officer on the basis of alleged prejudgment (from his participation as presiding officer in the aldrin-dieldrin proceedings and his role as presiding officer in the heptachlor-chlordane cancellation proceeding) and alleged bias in the conduct of the suspension hearing. I have rejected all of these allegations as being totally unfounded and without merit in fact or law. Judge Perlman has conducted these proceedings with admirable impartiality and fairness, and I have the highest regard for his abilities as a jurist, particularly in consideration of the extremely complicated nature of these proceedings. His experience, knowledge, and service in the public interest are invaluable.

[7] During the course of the suspension hearing Velsicol Chemical Corporation also petitioned the Administrator for review of Judge Perlman's August 6 order, asserting that the cancellation and suspension proceedings should go forward simultaneously. At the root of this issue was the question of whether Judge Perlman should rule on a motion pending in the cancellation proceeding seeking the appointment of a Committee of the National Academy of Sciences, pursuant to Section 6(d) of FIFRA. The National Agricultural Chemicals Association and the U.S. Department of Agriculture also petitioned the Administrator for review of the August 6 order, essentially on the same grounds. In the case of all three petitions, as well as a subsequent Velsicol petition for reconsideration, I denied the relief requested. I also dismissed Velsicol's suggestion that the Administrator be recused from the proceeding on the ground of prejudgment.

The hearing covered 43 hearing days and was closed on December 4.[8] Following the hearing, the parties submitted proposed findings and conclusions and briefs (on December 8), and Judge Perlman submitted his recommended findings and conclusions on December 12.

B. *The Recommended Decision*

In a 122-page Recommended Decision, Judge Perlman has set forth 95 Findings of Fact and 50 pages of Conclusions, leading to a proposed Order, which states: "By reason of the foregoing, the notice of intention to suspend is dismissed." A copy of the Recommended Decision is appended to this final Decision and Order. For the reasons stated herein, I adopt all 95 Findings of Fact set forth in the Recommended Decision and hereby specifically incorporate them by reference in this final Decision. Notwithstanding my agreement with the facts as found by Judge Perlman, I have reached different conclusions on some of the issues presented and, therefore, partially accept and partially reject his recommendations.

As will be seen herein, in partially rejecting Judge Perlman's recommended conclusions, I have in most instances substantially agreed with this assessment of the facts. The partial reversal results almost completely from the application of rules of law laid down by the FIFRA itself and by judicial decisions interpreting it. Indeed, I

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[8] At the request of Judge Perlman and for good cause, on November 25 I extended the hearing beyond the 40 days provided for in the notice of suspension to include an additional 10 days for rebuttal and surrebuttal evidence.

want to stress at this point my admiration for the masterful fashion in which Judge Perlman presided over these hearings. Under time constraints that may be described only as excruciating, he oversaw the amassing of 10,000 pages of transcript and an equal volume of exhibits. He did this knowledgeably, efficiently, sensibly, and with good humor, belying many hours of preparation outside the hearing room.

1. *Findings of Fact*

The facts found by the Administrative Law Judge ("ALJ") in this proceeding cover a wide range of items, including the identification of the sole manufacturer of technical grade heptachlor and chlordane, Velsicol Chemical Corporation ("Velsicol" or "registrant"), and the intervening parties; the chemical nature of qualities of heptachlor, chlordane, and their metabolites; the finding of residues of these chemicals in human adipose tissue, human milk, and human fetuses after passing through the placenta; the finding of residues in the ambient air, soil, bodies of water, fish, shellfish, mollusks, plankton, sediments, and so on; the finding of residues of these chemicals in dairy products, meat, fish and poultry and, to a lesser extent, in raw agricultural products by the U.S. Department of Agriculture and the Food and Drug Administration; the use of heptachlor and chlordane on vegetables and fruits, homes, lawns, and gardens by private homeowners and commercial pesticide control operators on crops such as corn, citrus, strawberries, tomatoes, and grapes, as well as on ornamentals, as seed treatment, and against specific pests; the findings regarding alternative pest controls for such uses; and the effects of the unavailability of heptachlor and chlordane which might result from suspension and continue for the duration of the cancellation proceeding.

I have reviewed the findings of fact contained in the Recommended Decision carefully and completely and, as

noted above, adopt them in full for purposes of this final Decision and Order.

2. *Conclusions*

As stated above, while I agree with Judge Perlman's findings of fact based on the record of this proceeding, I do not accept all of his conclusions.

A crucial question in this proceeding is the issue of carcinogenicity; that is, the issue of human cancer and whether the continued use of heptachlor and chlordane during the time required to reach a final decision in the cancellation proceeding creates an "imminent hazard" in terms of a human cancer risk. This proceeding is not concerned with other potential human health risks or with potential harm to the natural environment.

On the issue of carcinogenicity, Judge Perlman found that heptachlor, its metabolite, heptachlor epoxide, and chlordane "appear to be" carcinogens in the laboratory mouse and that heptachlor and heptachlor epoxide "may be" carcinogens in the laboratory rat.[9] He concluded, however, that he was "hesitantly unwilling at this time to find that heptachlor and chlordane are *conclusively* carcinogens in laboratory animals." (emphasis added.)[10]

In spite of the foregoing finding, Judge Perlman stated that he did not wish "to leave the impression that the safety of heptachlor and chlordane is not still a matter of grave concern."[11] In the statement of his ultimate conclusion on the issue of carcinogenicity, Judge Perlman said:

> In other words, [heptachlor and chlordane] are not "home free" by any means with respect to whether

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[9] Recomended Decision, p. 86.

[10] Recommended Decision, p. 86.

[11] Recommended Decision, p. 87.

> they are carcinogens in laboratory animals and a potential carcinogenic risk to man. We merely state that at this time we do not so conclude and, by reason thereof, we cannot find an "imminent hazard" with respect thereto.[12]

After so holding with respect to the risk to human health of the continued use of chlordane and heptachlor, the ALJ held that he need not consider the question of whether the economic, social, and environmental benefits of the [illegible] of heptachlor and chlordane during the time required to reach a final decision in the cancellation proceeding are sufficient to outweigh the risks of their continued use. Nonetheless, Judge Perlman proceeded to set forth his recommendations regarding the uses, benefits, and alternatives for heptachlor and chlordane "should the Administrator disagree with our findings [on carcinogenicity], as well as he might. . . ." [13]

As set forth in some detail in Part III of this Decision, Judge Perlman recommended that, assuming the Administrator disagreed with him on carcinogenicity, the major uses of heptachlor and chlordane (by volume), including use on corn crops and household uses, should be suspended because these uses would not provide sufficient benefits to justify their continuation pending completion of the cancellation proceeding. He also recommended, however, that many relatively minor uses not be suspended.

In sum, therefore, the ALJ's precise holding that there was no "imminent hazard", and thus no basis for suspension under section 6(c) of the FIFRA (1) was made without balancing the risks of continued use of chlordane and heptachlor against the benefits of that use, and (2) was grounded solely on the holding that he was "hesi-

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[12] Recommended Decision, p. 87.

[13] Recommended Decision, p. 88.

tantly unwilling" to find that chlordane and heptachlor are "conclusively" carcinogens in laboratory animals even though they both "appear to be" such carcinogens and the question of their safety on this score is "a matter of grave concern."

Both of these holdings contain misapplication of the pertinent statutory provisions and controlling judicial decisions.

Section 6(c)(1) of the FIFRA provides that the Administrator may suspend the registration of pesticides where "that action is necessary to prevent an imminent hazard during the time required for cancellation . . . proceedings. . . ."

The term "imminent hazard" is defined in Section 2(1), in pertinent part, as "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment . . ."

The phrase "unreasonable adverse effects on the environment", in turn, is defined in section 2(bb) to mean, "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."

Thus, in combination, sections 6(c)(1), 2(e), and 2(bb) provide that suspension depends upon a finding that continued use of a pesticide during the time required for a cancellation proceeding would be *likely* to result in any *unreasonable risk* to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide.

As the courts have held (and, indeed, as counsel for the registrant have urged in this proceeding), the question of the "reasonableness" of the risk presented depends upon an assessment of the nature and magnitude of risk of harm

to man or the environment as compared to the nature and magnitude of economic, social, and environmental benefits which are derived from the use the pesticide during the time required for a cancellation proceeding.[14]

Thus, the FIFRA and the cases, in my opinion, make two points clear with regard to a suspension proceeding. First, it is not necessary to find "conclusively" that actual harm to man will occur if the use of the pesticide in question is continued; rather the finding required is that continued use during the cancellation proceeding is "likely" to result in any "unreasonable risk" to man or the environment. As the court of appeals has held:

> [T]he term "imminent hazard" is not limited to a concept of crisis: "It is enough if there is *substantial likelihood* that serious harm will be experienced during the year or two required in realistic projection of the [cancellation] process."[15]

Second, the propriety of suspension turns upon an analysis in which the risks are balanced against the benefits, rather than from an analysis of risks or benefits alone.

It should also be noted that the mere fact that the evidence on either of these issues (risks or benefits) is not complete, or that more evidence may be expected to be developed in the cancellation proceeding, is not a reason to deny suspension. Suspension is an interim remedy, to be determined on a record assembled on an expedited basis, as was the case here. Congress must have expected that the record of a suspension proceeding would not contain all the evidence on crucial questions that would

[14] *Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F. 2d 1292, 1302 (C.A.D.C. 1975); *EDF* v. *EPA*, 465 F. 2d 528, 538 (C.A.D.C. 1972).

[15] *EDF* v. *EPA*, supra, 510 F. 2d at 1297, citing *EDF* v. *EPA*, supra, 465 F. 2d at 540.

be expected and presented in a cancellation proceeding. As the court of appeals has held:

> [T]he function of the suspension decision is to make a preliminary assessment of evidence and probabilities, not an ultimate resolution of difficult issues.[16]

For the foregoing reasons, I find that the ground given by the Administrative Law Judge in determining not to recommend suspension of the registrations of heptachlor and chlordane is deficient as a matter of law. He failed to weigh adequately the risks in relation to the benefits as required by the statute and by Agency policy. Moreover, he held that the fact that the carcinogenicity of heptachlor and chlordane had not been "conclusively" established with respect to laboratory animals was determinative of the potential risk of cancer to man, even though the statute talks in terms of the likelihood of an unreasonable risk. Indeed, I believe that this much less stringent statutory standard was met by Judge Perlman's findings that heptachlor and chlordane "appear to be" carcinogenic in laboratory animals and are pesticides whose safety is a matter of "grave concern."[17] In the same vein, the courts have also insisted that the burden of proof of the safety of a pesticide lies at all times with the registrant.[17a] Thus, insofar as the showing of risk of harm

[16] *EDF* v. *EPA*, supra, 510 F. 2d at 1298, citing *EDF* v. *EPA*, supra, 465 F. 2d at 537.

[17] In other words, when the correct legal standard is applied to the facts found by the ALJ, those facts themselves warrant, and indeed require, reversal of his ultimate decision. Thus, the registrant's assertion that particular deference should be paid to the ALJ's findings because of his great exeprience is something of a weak reed. (Velsicol's Brief in Support of Affirmance, at p. 41-42). Indeed the registrant admits that "there are certain findings and conclusions rendered by the Chief Administrative Law Judge . . . to which Velsicol objects. . . ." (*id.* at 40).

[17a] *E.g.*, *EDF* v. *EPA*, supra, 510 F. 2d at 1297; *Dow Chemical Co.* v. *Ruckelshaus*, 477 F. 2d 1317, 1324 (C.A. 8 1973).

from heptachlor and chlordane is not yet conclusive, it should be emphasized that it is not the Agency's burden to establish the risk of harm, but rather the registrant's burden to disprove it once its safety has been called into question by a sufficient showing of probable risk.

II. The Issue of Carcinogenicity of Heptachlor-Chlordane

As discussed in Part I of this Decision, I believe the ALJ's own findings of fact on carcinogenicity establish a "substantial likelihood" of harm when the proper legal standard is applied, sufficient to find an "imminent hazard." In combination with his findings as to benefits, this would require at least partial rejection of his recommended dismissal of the suspension notice. However, while I largely agree with the ALJ's specific findings on these issues, I do not agree entirely, and therefore will discuss the issue of carcinogenicity in this Part and the benefits issue in Part III of this Decision.

A. *Underlying Principles*

The Agency's experience and knowledge in the area of identifying substances which cause a risk of cancer in man continues to grow. In addition to my decision of October 1, 1974, on the suspension of aldrin and dieldrin [18] and the statements on the denial of the State of Louisiana's request for Emergency Use of DDT on Cotton,[19] the Agency has also, after lengthy study and consideration (including requests for and consideration of comments from all portions of the interested public), adopted procedures for reigstration, reregistration, and classification of pesticides, including a specific standard for determining whether a pesticide presents a risk of oncologic effects in man.[20]

[18] *In re Shell Chemical Company*, 39 Fed. Reg. 37265, 6 ERC 2047.

[19] 40 Fed. Reg. 1934, 15949 (April 8, 1975).

[20] 40 Fed. Reg. 28242, 28254-28257, 28262-28264 (July 3, 1975).

In view of the Agency's developed experience and knowledge in this area, the notice of intent to suspend (together with the clarifying order of August 6) provided a statement of the principles and policy that would be applied in this proceeding. The record in this proceeding confirms the correctness of these principles.[21]

[21] Registrant raises again before me both an objection to the *ex parte* communication leading to the August 6 order of clarification and to the procedure set out in that order for submission of evidence on this issue. As to the first point, I believe it to be insubstantial, at least for the reasons stated by the ALJ in his Recommended Decision. See pages 117-120. As to the second point, I cannot see that any harm whatsoever has been done to the registrant. Early in the suspension hearing the registrant complained to the ALJ that it had been foreclosed by the suspension notice from presenting evidence on the issues discussed in the notice. However, the August 6 order made it clear that the registrant could present such evidence, thus giving the registrant exactly what it had asked. Now, seeking to show *some* harm that it has suffered on this account, the registrant argues that, had the contact between the Office of General Counsel and the Deputy Administrator not been *ex parte*, the registrant might have been able to convince the Deputy Administrator in addition to place upon the Agency the burden of going forward with evidence on this issue. I do not believe that such an argument, even if correct, amounts to any significant detriment to the registrant in view of the clarity of the statements made in the notice of suspension as to the points in issue. Equally important, however, I am not convinced that the registrant is being entirely candid in raising this argument before me. The fact is that, at the very beginning of the hearing, the respondent did introduce into evidence as part of the testimony of Dr. Epstein an article by Dr. Epstein entitled "Environmental Determinants of Human Cancer," *Journal of Cancer Research*, October 1974, pages 2425-2435, EPA Ex. 8, App. 2. This evidence comprehensively covers the points discussed in the suspension notice, and thus constituted a "going forward" with the evidence (and more) that registrant now argues respondent did not do, but might have done. Moreover, counsel for registrant was well aware of this portion of Dr. Epstein's testimony and objected to its admission into evidence, which objection was quite properly overruled by the ALJ. Tr. 503-507. In sum, I do not find any merit whatever in the registrant's contention.

It is generally not possible to obtain sufficient information to determine whether particular substances that are widespread in the environment in small amounts cause cancer in man. The fact of wide distribution makes it impossible to compare the reaction of those persons who are exposed to the substance with those who are not, since people in the latter category cannot be found. Similarly, for obvious reasons, studies in which artificially high levels of a suspected carcinogen are intentionally given to a test group are not performed on humans. Situations where this occurs by accident are rare and not subject to control.

In addition, the latency periods for cancer-inducing chemicals tend to be long (in the tens of years), so that what results there are from the study of human exposure are difficult to gather and may well appear too late to save people from an already widespread chemical to which they are unavoidably exposed.

For these reasons, pesticides and other chemicals are tested for carcinogenicity in laboratory animals, particularly mice (the first choice) and rats, which are broadly accepted by the scientific community as appropriate test animals for these purposes.

The mouse develops almost every kind of cancer that occurs in man and, with few, if any, exceptions, is subject to cancer from any source which is known to be a carcinogen in man. In both mouse and man, genes are involved in the control of processes through which cancer is induced. They control reactions to physical and chemical carcinogens. The genetic characteristics of mouse and man are sufficiently similar to permit the assumption that if a chemical or other agent (such as radiation) causes cancer in a particular organ of mice, then it will also cause cancer in the same organ, or possibly some other organ, of man.[22]

[22] EPA Ex. 44, at pp. 9-10 (testimony of Dr. Heston); EPA Ex. 8, App. 2, at pp. 2427-2428 (Dr. Epstein).

In fact, the difficulty with using laboratory animals to test for carcinogenicity lies in the other direction. The failure of a chemical to induce cancers in a particular strain (or even several strains) of laboratory animals is not an assurance that the chemical is not a carcinogen in man, since that particular strain may be genetically resistant to cancer from that source; where, by contrast, the genetic susceptibility of people to cancer varies a great deal from person to person.[23]

Some interest has focused on the high dose levels given to laboratory animals as opposed to the much lower levels encountered by man in the environment, the supposition being that the lower doses naturally encountered may not be dangerous. However, there is not any evidence to indicate that there is a minimum dosage of any known carcinogen below which it does not have a carcinogenic effect.[24] There does appear to be a relationship between the dose level of a carcinogen on the one hand and, on the other, both the percentage of the total of persons or animals exposed who get cancer and the latency period of the disease. High doses in animal experiments are thus justified, and indeed necessary, because the comparatively small numbers of animals necessarily involved in the experiments make it very difficult at least to test for positive results at lower doses.

> Testing at . . . relatively high doses is now generally regarded as essential to the attempt to reduce the gross insensitivity imposed on tests by the small size of animal groups routinely tested, such as 50 or so rats or mice per dose level per chemical, compared with the millions of humans at presumptive risk . . . .
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> To illustrate the insensitvity of conventional animal test systems, assume that man is as sensitive to a

[23] EPA Ex. 44, pp. 6, 13-14.

[24] EPA Ex. 45A, pp. 16-17; EPA Ex. 8 App., p. 2427.

particular carcinogen as the rat or mouse. Assume further that this particular agent carries a risk of producing cancer in 1 of 10,000 humans exposed; this would result in approximately 20,000 cancers in the United States population. Then the chances of detecting this in groups of 50 rats or mice, tested at ambient human exposure levels, are very low. Indeed, samples of 10,000 rats or mice would be required to yield 1 cancer, over and above any spontaneous occurrences, for statistical significance, perhaps 30,000 rodents would be needed.[25]

Moreover, there exists the problem that for particular chemicals, human beings may be far more sensitive than laboratory animals. For example, thalidomide produces teratogenic effects in man at a dose level that is 1/60 of that needed to produce that effect in mice, 1/100 of that for rats, 1/200 of that for dogs, and 1/700 of that for hamsters.

Finally, I have noted some tendency, not entirely absent from the record, to assert that any chemical, if fed in sufficiently large amounts, will cause cancer in test animals. This is not true. A study sponsored by the National Cancer Institute tested 140 pesticides and industrial chemicals in two strains of mice; less than ten percent of these were found to be carcinogenic.[26]

One of the registrant's witnesses, Dr. Coulston, a toxicologist, did testify, using generalized and unsupported broad

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[25] EPA EX. 8, App. 2, p. 2427 (Dr. Epstein); Tr. 568-69.

[26] See EPA Ex. 8, App. 2, p. 2428. There is also an interesting tale of an experiment which allegedly showed that table salt was carcinogenic. The record reveals that an experiment has been performed in which, when fed to mice along with two known carcinogens, table salt increased the incidence of cancer, but only because it eroded the lining of the stomach and permitted the carcinogens a better opportunity to come into contact with the cells they affect. Tr. 8561-8562.

statements, that laboratory animal studies are an inadequate substitute for epidemiological studies in man. He stated that "a study on workers with high degrees of exposure is far more valuable than a study exposing 200 or 2000 mice."[27] However, in the same paragraph he conceded that a single epidemiological study is not conclusive. Indeed, evidence was introduced into this record as to three epidemiological studies, two of field workers and one of persons employed in the manufacture of heptachlor and chlordane. Owing to the difficulties of low numbers of subjects, lack of proper controls (*i.e.*, other persons with precisely the same environment, but not exposed to these pesticides), inability to track down persons and obtain precise diagnoses, short duration of the studies as compared to expected cancer latency periods, difficulty in obtaining data from subjects,[28] the fact that subjects were not representative of the whole population, and similar problems, Registrant and USDA witnesses who presented this

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[27] Vel. Ex. 40, p. 10.

[28] Dr. Samuel Sandifer had conducted a study of 57 North Carolina field workers who had applied heptachlor and chlordane. On cross-examination, Dr. Sandifer was asked whether samples of the fat of these workers had been analyzed; this is of obvious importance since heptachlor and chlordane like other chlorinated hydrocarbons, are soluble in lipid tissue, and it is in such tissue that the highest residues of these chemicals are found in humans. The exchange thus occasioned is symptomatic of the great difficulty in conducting studies on humans:

> Q. [by Mr. Lee] Were any adipose samples taken from any of the subjects?
>
> A. [by Dr. Sandifer] Not in this group.
>
> Q. Was there any reason by they were not taken?
>
> A. People did not want to have them done. We had enough trouble getting blood. They would not stay with us.
>
> JUDGE PERLMAN. They would not stand for it?
>
> [Dr. Sandifer]. That is right. We didn't even ask them, to tell the truth. We thought it was an unreasonable request. Tr. 7730-7731.

testimony uniformly agreed that the results were at best inconclusive.[29]

Thus, contrary to Dr. Coulston's claim, the present record confirms that human epidemiological studies are by their nature inadequate, and his testimony did not suggest any method to improve such studies. Indeed, Dr. Coulston at least implicitly admitted that the animal tests upon which the present result is based do serve as proper ground for the suspension action taken.

> JUDGE PERLMAN . . . [W]hat did you mean when you said . . . that if you find a chemical that doesn't produce the same results in laboratory animals that we should use the other chemicals . . .?
>
> [Dr. Coulston] That means exactly what it says . . . Obviously if you have alternatives that will substitute, let's say, for chlordane, and the benefits are equal, and if the alternative was such a chemical that did not produce hepatomas, et cetera, et cetera, one would be foolish not to say, "I would take the alternate," if there were such an alternate, of equal benefit.[30]

Thus, despite his other testimony, Dr. Coulston actually confirmed, from a scientific point of view, a course of benefit-risk analysis based on laboratory animal experiments which is quite similar to that followed here.

B. *Evidence of Carcinogenicity*

The evidence of carcinogenicity of heptachlor and chlordane in mice and rats rested upon a series of animal studies. In addition to the diagnosis made during the studies, rediagnoses were made of slides of organs by experts for both the registrant and respondent.

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[29] Tr. 3632-3634, 3643, 7728-7736, 7955-7966. See Respondent's Final Brief, at pp. 182-194.

[30] Tr. 7856-7857; see 7851.

With respect to chlordane, there exist a Velsicol-commissioned study on the mouse by the International Research and Development Corporation (IRDC), and a preliminary version of a National Cancer Institute-sponsored study on the mouse by Gulf South Research Institute (GSRI).

With respect to heptachlor and heptachlor epoxide, there are a Velsicol-commissioned IRDC mouse study, a Food and Drug Administration mouse study, preliminary NCI/GSRI studies on mice and rats, a 1959 Kettering Laboratory study on the rat, and certain other studies.

With the exception of the NCI/GSRI studies, whose results are still in preliminary form, all or part of the slides generated by the other studies were reviewed in a "blind" fashion (*i.e.*, without any labeling as to whether the rat in question was male or female, a test or control animal, etc.) by Doctors Reuber, Stewart, Squire, and Williams. Dr. Popper reviewed slides from the IRDC chlordane study and the 1959 Kettering rat study.

Doctors Popper and Stewart have extraordinary, and perhaps unparalleled credentials for diagnosing mouse and rat tumors, and Dr. Reuber has performed an unusual and impressive amount of work in this specific area.

The diagnoses and testimony of these expert scientists, along with that of Dr. Epstein and Dr. Gross (who analyzed the results for statistical significance) are highly persuasive of the carcinogenicity of chlordane and heptachlor in mice, and of heptachlor in rats.

Quite apart from the convincing nature of that testimony, the record also shows that the registrant submitted slides from certain of the studies to other experts, in particular, Doctors Becker, Newberne, Steinberg, Deichman, and McDonald, for the apparent purpose of determining whether they should be asked to testify. These doctors submitted reports to the registant indicating their view that

the slides showed cancers.[31] These reports confirm the finding of carcinogenicity. In addition, none of these experts was called by the registrant to testify.

Judge Perlman was unwilling, in his recommendations, to give any weight ot the NCI/GSRI mouse studies because of "serious questions as to the protocols therein, that is, with respect to the size of the control group and the dosage fed . . . ." [32] I have carefully reviewed the evidence as to this study, and I do not believe that Judge Perlman's reluctance to give weight to the NCI/GSRI experiments is justified. The exact doses of chlordane and heptachlor were changed downward during the experiment because they appeared originally to be so high as to be inducing an acute toxic effect. The downward adjustment means at most that the actual feeding levels can only be estimated within certain limits, but that does not disqualify the entire experiment for the general question of whether these chemicals are carcinogenic. Moreover, as Dr. Epstein testified, the low number of control animals (10 per group), as compared to the test animals, actually makes the experiment *less* sensitive to a positive result. In other words, the small number of controls makes it statistically much more difficult to demonstrate a positive result. In Dr. Epstein's words, the NCI/GSRI studies, which have only ten controls, "are massively loaded against finding a positive result." [33] Therefore, I regard this particular deficiency in method as actually increasing the reliability of the positive results that Dr. Epstein reported from the preliminary reports of the NCI/GSRI studies, and confirming

[31] EPA Exs. 5, 7, 8, 29, 41.

[32] Recommended Decision, p. 80.

[33] Tr. 569. Dr. Epstein also testified that this kind of insensitivity of the experiments may also be responsible for the absence of positive results at lower feeding levels. Tr. 568-69.

the finding that chlordane and heptachlor are carcinogens in mice.[34]

The major issue in this proceeding with respect to the pathology of the lesions induced in laboratory animals in these studies has centered on the asserted insufficient finding of invasion or metastasis.[35]

The registrant has argued that in the absence of invasion or metastasis, cancer simply cannot be diagnosed, and that a requirement of invasion or metastasis for a diagnosis of cancer is necessary to avoid diagnosis on "subjective" bases.

As discussed elsewhere herein, the ALJ was impressed to some degree by this argument and the testimony of Doctors Rust and Butler for the registrant. It is important to note, however, that the ALJ's concern on this issue was sufficient only to make him "hesitantly unwilling at this time" to find that heptachlor and chlordane are "conclusively" carcinogens in laboratory animals.

I have concluded, as discussed above, that this admittedly hesitant reluctance to make a conclusive finding at this point is not a legally sufficient ground to refuse the finding of "significant likelihood" of harm that is necessary for suspension under the FIFRA and controlling legal precedent. Therefore, to deny suspension on this issue I

[34] In addition, in view of Dr. Gross's testimony as to the statistical significance of the results of the 1959 Kettering rat study (EPA Ex. 12, at 3-5), the very low natural incidence of tumors in rats, and Dr. Popper's conclusion from study of slides from this experiment that "I am convinced that this is one of the most potent carcinogens of which I can recall," (EPA Ex. 9; Tr. p. 22), I conclude that heptachlor is a carcinogen in the rat, as well as the mouse.

[35] "Invasion" is the spreading of the tumor into surrounding tissue, and "metastasis" is the spreading of cancer to the organs. These are the effects of malignant tumors which are most harmful to the host animal.

would have to find the registrant's evidence on this point to the stronger than did the ALJ. On the basis of the present record, however, I cannot make such a finding. Indeed, I do not find the registrant's evidence to be at all convincing.

At the outset of this discussion, it should be stressed that the low number of findings of invasion and metastasis in the treated animals in the studies involved does not mean that those developments were sought after and not found. Quite the opposite is true. The techniques (primarily the new technique of serial sectioning, or taking many slides rather than just one slide of the organs affected) necessary to look comprehensively for invasion and metastasis were not employed in the studies involved here. Moreover, many test animals were sacrificed too early for metastasi to have developed more significantly. Indeed, there was evidence in the record that on the basis of the smaller degree of incidence of invasion and metastasis found here, a much larger percentage would have been found had serial sectioning been employed.[36] Moreover, the record shows that cancer should be diagnosed not only with respect to those lesions that have demonstrated metastasis or invasion, but also with respect to those that have the capacity to metastasize and invade even though they may not yet have done so.[37]

It is also of extreme importance to characterize this argument properly on the basis of the testimony of Doctors Butler and Rust. Neither testified that it is never possible to diagnose cancer from slides of the lesion itself without evidence of invasion or metastasis. Rather, both testified that this is a matter of degree, and, assuming sufficient familiarity with the species of animal, the organ,

[36] EPA Ex. 31.

[37] Tr. 676-680 (Dr. Stewart); EPA Ex. 2, p. 8 (Dr. Reuber); Tr. 716 (Dr. Squire).

and the tumor in question, it is possible to diagnose cancer on the basis of a slide of the lesion without evidence of invasion or metastasis. In their view, however, experience with the mouse and heptachlor and chlordane are too limited to provide the basis for judgments as to carcinogenicity without a finding of invasion or metastasis.[38]

Thus, Rust, and particularly Butler, are generally less willing to make the leap than the other doctors whose diagoses are involved here, since no other expert refused to make a diagnosis on this basis. To disagree with the conclusion of Doctors Rust and Butler as to the ability to diagnose liver cancer in the mouse strictly on the basis of study of the lesions themselves, then, it is not necessary to disagree in any radical way with a medical theory; rather one must be more knowledgeable about the mouse liver and tumors therein, or more confident about the implications of what one observes. On this record, considering the great erudition and experience of the respondent's witnesses in this field, I am not willing to discredit their conclusions that cancer in the mouse liver can reliably be diagnosed on histologic evidence alone.

This conclusion is buttressed by a feature of Dr. Rust's testimony that calls his testimony on this point into some doubt. In 1972, the registrant sent Dr. Rust a series of slides of livers of mice fed heptachlor, with some slides of control mice and some of "positive controls" (that is, mice fed a known carcinogen). Dr. Rust reviewed the slides and sent the registrant a 34-page report diagnosing the slides. In the conclusion of the report, Dr. Rust stated, "It is quite clear that the test animals were subjected to a severe hepatatoxin and carcinogen." [39]

This conclusion was made without any statement of whether invasion of metastasis had been observed. Dr.

[38] Tr. 3390-3402; 3856-3857.

[39] EPA Ex. 6, p. 31.

Rust later changed this conclusion, testifying at the hearing that the change came about because he had previously been unaware that slides from positive controls had been included in those submitted to him in 1972.[40] This may explain the change in conclusion as to the carcinogenicity of the pesticide (an explanation which the ALJ tended to credit). However, it does not explain why in the 1972 report Dr. Rust was willing to conclude that whatever had caused the lesions in questions was a carcinogen without making any prominent mention (and, apparently, with no mention at all) of either invasion or metastasis. Dr. Rust did testify at the hearing that he had found invasion in 1972.[41] Even if he did, however, the fact that that finding was not featured in his written 1972 report and diagnosis casts grave doubt on the credibility of Dr. Rust's current testimony as to his view of the crucial importance of a finding of invasion or metastasis to a conclusion of carcinogenicity. In addition, Dr. Rust's rather emotional outbursts and his apparent emotional commitment on this issue, while perhaps providing a leavening influence on the hearings, unfortunately also limit the value of his testimony.[42]

For these reasons, I do not believe that the question of invasion and metastasis is as important as the registrant argues, and I cannot conclude that the testimony of Doctors Butler and Rust discredits the diagnoses of the respondent's experts.

A related argument by the registrant is that the so-called "subjective" diagnoses by the respondent's expert pathologists are frequently in conflict, and that this supports the argument that an "objective" standard—namely, one requiring a finding of invasion or metastasis—is preferable. As the ALJ found, however, these asserted dis-

[40] Tr. 3849-3852.

[41] Tr. 3850.

[42] Tr. 3837-3839.

agreements are not substantial. In the first place, the registrant has a tendency to point to varying diagnoses of individual slides, ignoring the overall agreement of the diagnoses. It would be surprising indeed if there were no differences of opinion at all among these pathologists. Moreover, as the ALJ also found, a great deal of the apparent difference is due to varying nomenclature for the same events, a situation which is made more difficult by the fact that the nomenclature still is in a state of some flux. There appeared to be very substantial agreement among the respondent's experts on which lesions were reversible if the stimulus were withdrawn, which had passed to a point where they might reverse and they might not, and which were irreversible.[43]

The registrant also has elaborately argued that a mathematical model, called the Mantel-Bryan formula after its developers, can be used to show that the level of heptachlor and chlordane in the environment is so small that it would be "safe"; that is, it would cause a very small number of cancers. In addition to noting that Dr. Mantel himself severely criticized the use of the variants of his formula by the registrant's witness as very insufficiently conservative,[44] I agree with the ALJ's conclusion [45] that this entire

[43] The process of development of tumors in mouse livers is continuous. The earliest stage is a small abnormal cluster of liver cells, five to ten cells in diameter, called dyspasia or early hyperplasia. This lesion may well regress if the carcinogen is no longer applied. As the lesion expands in size and compresses the surrounding cells, it becomes a hyperplastic nodule. Some of these nodules will regress if the carcinogen is withdrawn and some will not, but will progress further to carcinomas. Because it is not at present possible to tell which will regress and which will not, and because these nodules are caused only by carcinogens, there has been a recent trend to call them neoplastic nodules, but this change or difference in nomenclature is not significant to diagnoses. See Tr. 408-414; EPA Exs. 2, 3, 4.

[44] EPA Ex. 43, pp. 5-13.

[45] Recomended Decision, pp. 86-86, note 25.

line of analysis is unreliable because of the incomplete assumptions made by the registrant's witnesses about the sources of human exposure in the environment, the natural variation in human susceptability to cancer, the lack of any evidence relating the level of human susceptability to cancer from heptachlor and chlordane as opposed to that of the mouse, and the absence of precise knowledge as to the minimum exposure to a carcinogen necessary to cause cancer. As the ALJ noted, mathematical modeling to show the risk of cancer is in its very infancy; it is not now useful to establish "safe" levels of exposure.

Late in the hearing, the registrant produced and introduced into evidence a copy of a "working draft" of a subcommittee on environmental carcinogens of the National Cancer Advisory Board,[46] asserting broadly that this document casts grave doubt upon the methodology employed by the respondent herein to establish carcinogenicity.[47] In addition to the facts that this is only a non-final working draft, that little was shown about the qualification of the committee, and that nothing is known about the import the committee intended the rather vaguely worded working draft to have, no witness from the subcommittee appeared to testify as to these questions or the draft itself. The witness through whom the ALJ permitted these documents into evidence know practically nothing about them.[48] As

[46] Vel. Ex. 45.

[47] Registrant's Supplemental and Reply Brief, p. 4ff.

[48] Tr. 8651-8652, 8661-8663. The respondent included in its final brief material from a transcript of subcommittee deliberations on the working draft. On motion of the registrant, the ALJ held that this material was not in evidence and could not be considered. While that holding was correct, I do note that the registrant attempted to read from the same transcript at the hearing. Tr. 8663-8664. Obviously, some such explanatory material would be necessary to render the working draft sufficiently comprehensible for use in a proceeding like the present.

such the draft is almost completely worthless as evidence. Moreover, the language of the draft itself will not at all bear the weight the registrant seeks to put on it. For example, the registrant cites a statement in the draft that experiments using experimental animals with "very high spontaneous frequency of a particular tumor" "do not in themselves constitute definitive evidence for carcinogenicity."[49] The registrant does not quote the following sentence, "Positive results in such procedures do suggest, however, that the compound is potentially carcinogenic and therefore warrants further study." Moreover, of course, the draft does not make clear what "definitive" means or how high a "very high spontaneous frequency of a particular tumor" is. In this proceeding, Dr. Heston testified convincingly that the C3H mouse used in the FDA study here did not have such high levels of spontaneous tumors as to render the results unreliable, and that, in any event, the mice used in the NCI/GSRI and IRDC studies had much lower natural incidences of tumors.[50] This point from the subcommittee draft thus has little, of any, weight for present purposes.

The subcommittee draft also states that studies "in which the test compound causes a significant and reproducible increase in only benign tumors" do not in themselves constitute "definitive evidence of carcinogenicity" but suggest that "the compound is potentially carcinogenic"; the draft goes on to say, "Further testing is particularly indicated if the compound induces benign tumors since it is known that such compounds when adequately studies [sic] often induce malignant tumors."[51] Even taken at face value, and even assuming that "only" benign tumors had been shown in the pertinent studies, this

[49] Registrant's Supplemental and Reply Brief, p. 7, quoting Vel. Ex. 45, p. 2.

[50] Tr. 8580-8581.

[51] Vel. Ex. 45, pp. 2-3.

statement is not at all reassuring as to the carcinogenicity of heptachlor and chlordane. In addition, some invasion and metastasis were found (although not enough to satisfy Doctors Butler and Rust) in the studies here involved, and thus these studies did not produce "only" benign tumors. Moreover, I am convinced that, in view of the diagnoses of Doctors Popper, Stewart, and Reuber, and the work reflected EPA Exhibit 31, that had the most modern serial sectioning techniques been employed, more incidences of metastasis and invasion would have been found. For these reasons as well, I cannot give the draft subcommittee report significant weight.

Finally, the registrant argues that even assuming that chlordane and heptachlor are carcinogenic, their persistence in the environment, the slowness with which they degrade and the long latency period of cancer will combine to prevent an appreciable health benefit from accruing to man from cessation of their use for the year, 18 months, or more that the cancellation proceeding will be in effect.[52] This line of reasoning is not satisfactory. First, it is an established Agency principle that an imminent hazard "may be declared at any point of a chain of events which may ultimately result in harm to the public."[53] Thus, the fact that harm may not actually result during the cancellation process is not significant if the use of heptachlor and chlordane during that period would irreversibly create a risk of harm at a later time. Moreover, aside from specula-

[52] The registrant introduced evidence to show that the decline of DDT residues in food crops was slow after cancellation in 1972. Vel. Ex. 4. However, on cross-examination it was established that DDT use on food crops was rapidly declining in any event in the years before cancellation and that those declines in use were quickly followed by declines in residues of DDT and its metabolites in food crops. Tr. 7346-7353.

[53] Reasons Underlying the Registration Decisions Concerning Products Containing DDT, 2,4,5-T, Aldrin and Dieldrin, (March 18, 1971), p. 6.

tion, in view of the failure of the registrant to adduce evidence that it would be safe to continue to permit release of these pesticides for the period of the cancellation proceeding, and in view of the evidence as to their carcinogenicity, the widely varying susceptability of individuals to cancer, and the presence of heptachlor and chlordane in the environment for more than 18 years, I cannot agree that their use during the cancellation proceeding would not involve a substantial likelihood that serious harm would result.

III. The Uses, Benefits, and Alternatives For Heptachlor-Chlordane

A. *Relevance of the Benefits Issue*

As discussed above in Section II, the FIFRA requires that the Administrator take into account the economic, social, and environmental costs and *benefits* of the use of any pesticide in determining whether its continued use during the time required for completion of the cancellation proceeding would be likely to result in "any unreasonable risk to man or the environment." As noted previously, I have concluded that the ALJ did not conduct adequately the kind of risk/benefit balancing process which the law and Agency policy requires and, therefore, I am setting forth in this part my findings and conclusions on the relationship between the risks and benefits of specific heptachlor and chlordane uses. This part also considers the availability of alternative pesticides.

In my decision last year on the suspension of aldrin-dieldrin, I noted that in a suspension proceeding, unlike a cancellation action, EPA is not specifically required to balance possible benefits against the environmental and health risks of pesticide use. In that opinion, I also cited the language of the court of appeals, to the effect that: "We do not say that there is an absolute need for analysis of benefits."[54] The court, in reaching that conclusion, stated:

[54] *EDF* v. *EPA*, *supra*, 465 F. 2d at 540.

> We are not clear that the FIFRA requires separate analysis of benefits at the suspension stage. We are clear that the statute empowers the Administrator to take account of benefits or their absence as affecting imminency of hazard.[55]

Here, as in the aldrin-dieldrin case, however, I will follow the Agency policy of considering the benefits in relation to the risks of continued use of heptachlor and chlordane during the cancellation process. It is particularly appropriate, in view of the findings and conclusions contained herein relating to the issue of carcinogenicity and human health risks, that the particular uses and benefits of heptachlor and chlordane be addressed in some detail. This risk/benefits analysis is also appropriate since I have concluded, because of the varying degrees of risk and benefits associated with particular uses, that some uses should be suspended and others should not.

It should be emphasized that, in carrying out the risk/benefit balancing process, I have followed the rule that, "The responsibility to demonstrate that the benefits outweigh the risks is upon the proponents of continued registration."[56] I should also note that, in addressing the limited time available to the Administrator (seven days) and the question of how much *detail* Congress contemplated would be required of the Administrator's findings, the court of appeals in the aldrin-dieldrin case indicated that the law does not require "explicit evaluation of all relevant testimony when that is not necessary to deal with the salient grounds of objection and would preclude practical use of the suspension provisions."[57] The court of ap-

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[55] *EDF* v. *EPA*, *supra*, 465 F. 2d at 538.

[56] *EDF* v. *EPA*, *supra*, 10 F. 2d at 1302. See also *EDF* v. *EPA*, supra, 465 F. 2d at 532; *EDF* v. *Ruckelshaus*, *supra*, 439 F. 2d at 592 n. 22.

[57] *EDF* v. *EPA*, *supra*, 10 F. 2d at 1304.

peals concluded that it is sufficient "that there is substantial evidence in the record and that the court is able to discern the *fair import* of the Administrator's reasoning" (emphasis added).[58] Also, in keeping with the above, I will not in this Decision unduly recite the findings and reasoning of the ALJ except where a difference is made explicit and elaboration is necessary.

The uses of heptachlor and chlordane can be divided into two general categories: agricultural and non-agricultural. The former includes soil treatments to control various insects associated with the production of corn, citrus, peanuts, pineapple, strawberries, certain vegetables and fruits, and other miscellaneous crops. It also includes the treatment or dressing of corn, sorghum, and small grain seeds. The non-agricultural category (referred to by the registrant as "Public Health and Environmental Quality" uses) includes uses to control various lawn and turf insects, household pests (structural and non-structural), narcissus bulb pests, harvester ants, imported fire ants, ticks and chiggers, and as a constituent in shelf paper. The non-agricultural category also includes Federal quarantine programs to control the Japanese beetle and the imported fire ant.

B. *Non-agricultural Uses*

The principal non-agricultural uses of chlordane and heptachlor subject to this proceeding include their use against various household and lawn insects (both by private homeowners and by commercial pesticide control operators (PCO's)), use against various biting and stinging insects (harvester ants, fire ants, ticks and chiggers), and for purposes of Federal and State quarantine programs to control a few specific pests.

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[58] *EDF* v. *EPA*, 510 F. 2d at 1304.

The ALJ recommended that, as to these non-agricultural uses, the use of *heptachlor* be continued to control the narcissus bulb fly and the use of *chlordane* be continued for use in the Federal-State quarantine programs involving the Japanese beetle and the imported fire ant, in the Michigan quarantine program involving the black vine weevil,[59] for the control of the harvester ant in the State of Oklahoma,[60] and for use against the imported fire ant in the Southern States.[61] He also recommended, however, that the use of chlordane against non-wood destroying (*i.e.* non-structural) household insects (including lawn and turf insects), as well as the use of chlordane against wood-destroying (*i.e.* structural) insects, be suspended. He further found no need to continue the use of chlordane against ticks and chiggers [62] or as a constituent in shelf paper.[63]

Two actions taken by the parties late in the course of this proceeding with regard to the non-agricultural uses of chlordane and heptachlor also must be considered at this point. On November 25, 1975, the registrant submitted a letter regarding a voluntary curtailment of domestic shipments of heptachlor. In that letter, the registrant made a

[59] The ALJ was unaware of any other state quarantine programs for similar purposes, and therefore limited his recommendation to the Michigan program. He also concluded that the need for chlordane for nursery use against the black vine weevil was insufficiently documented in the record to justify a specific recommendation. Recommended Decision, pp. 94-95.

[60] The ALJ expressly limited this recommendation to Oklahoma, since the record did not indicate that the same problem existed in other areas.

[61] The ALJ conditioned this recommendation expressly on the doubtful availability of mirex bait, and recommended that this proceeding could be reopened should mirex become available for use against the fire ant.

[62] Recommended Decision, p. 98, note 35.

[63] Recommended Decision, p. 102, note 37.

commitment to restrict domestic shipments of heptachlor to use for termite control until a decision is reached on suspension, and thereafter, during the pendency of the cancellation proceeding, to voluntarily restrict heptachlor domestic shipments to uses for *termites, seed treatment, fire ants,* and *pineapples,* even if the Administrator decides not to suspend the use of heptachlor.

The import of the registrant's commitment is that it amounts to a voluntary suspension of heptachlor use on narcissus bulbs (except, presumably, to the extent that existing stocks may be available for this use) and for use by PCO's (*i.e.*, on household pests, other than termites). Although narcissus bulb use involves an extremely limited amount of heptachlor (approximately 200 pounds in the State of Washington, and even less in Oregon, with the Northwest being the major narcissus producing area), PCO use in 1974 accounted for 26.8 percent of all heptachlor use. The registrant's commitment also, however, indicates a strong belief on its part that the use of heptachlor against fire ants (which accounted for almost 2 percent of heptachlor use in 1974) is necessary during 1976.

The second of the two actions referred to above involves a statement made by the respondent, in its Exceptions to the Recommended Decision of the Presiding Officer filed on December 16, as follows:

> We do not contest dismissal of the suspension notice as to the following uses which should be more fully considered in cancellation and with respect to which the ALJ found that there are no adequate substitutes:[64]

Following the above statement is a listing of several uses of heptachlor and chlordane, including the following non-agricultural uses:

[64] Respondent's Exceptions to the Presiding Officer's Recommended Decision, p. 4.

Heptachlor:—narcissus bulbs

Chlordane: —Federal quarantine for Japanese beetle and fire ants
—fire ant, if mirex is unavailable
—harvester ant in Oklahoma[45]

The effect of the respondent's statement is a voluntary agreement not to pursue suspension of the foregoing uses of heptachlor and chlordane. Respondent apparently concedes the need, at least in 1976, for the use of *heptachlor* on narcissus bulbs, presumably because of the small amount involved and the fact that it is a non-food related use. Respondent's concession on the aforementioned *chlordane* uses is more significant, since they involve a broader range of use and significant amounts of chlordane (although the amount used for these purposes in 1974 apparently is not quantified in the record). I must also conclude from the respondent's exceptions that it agrees with the ALJ's recommendation that the use of chlordane against ticks and chiggers and as a constituent in shelf paper, be suspended.

The major import of the respondent's statement, with respect to non-agricultural uses, is that it strongly urges the suspension of home, lawn, garden and turf use (representing approximately 36 percent of total production of chlordane in 1974, or more than 7½ million pounds) because "there are adequate substitutes (as the ALJ found ...)—and even if adequate substitutes were not always available, the benefits from the home, lawn, garden and turf used of Heptachlor/Chlordane simply do not justify the resulting widespread exposure of the population to a potential carcinogen."

In view of the ALJ's recommendations and the actions taken by the registrant and the respondent, I am tempted to conclude summarily that certain non-agricultural uses

[45] *Ibid.*

of heptachlor and chlordane—not including home, garden, lawn, and turf used by homeowners and PCO's—can be resolved without any extended consideration of the relative risks and benefits associated with each specific non-agricultural use. In spite of the foregoing, I feel compelled to state my understanding and assessment of the risks and benefits of each of these uses.

1. *Narcissus Bulbs*

A very small amount of heptachlor is used to treat against the narcissus bulb fly by dipping bulbs prior to planting. About 200 pounds are used for this purpose annually in the State of Washington, and even a smaller amount in Oregon. The total acreage of narcissi (or daffodils) grown in Washington, Oregon, New Jersey, California, Virginia, and North Carolina is only about 1,800 acres. The value of the narcissus crop in Washington and Oregon is approximately $2 million.

It is apparent from the record that there is not now an effective, economical alternative to heptachlor for this use. The only alternative suggested was Dylox, which might be as much as 43 times more expensive to apply than heptachlor. Dr. Getzin estimated that about 3.5 percent of the Washington-Oregon crop would become infested in 1976, creating a severe economic threat.[46]

In view of the foregoing, I agree with ALJ's recommendation that the use of heptachlor for this purpose be continued, particularly in view of the fact that such a minute quantity is used and the risk of exposure to humans is negligible.

2. *Federal-State Quarantine Programs for Japanese Beetles and Fire Ants*

The Congress has enacted various statutes pursuant to which the United State Department of Agriculture

[46] USDA Ex. 9, p. 5.

(USDA) has established and administers the Plant Protection and Quarantine Program in cooperation with State governments for the eradication, prevention, or control of certain pests and insects whose movement or spread could create a hazard or economic loss potential.

The Japanese Beetle and imported fire ant are such an insect and pest, respectively. One regulatory program under the overall program requires, *inter alia,* that nursery stock whose movement out of the quarantine area presents a hazard of spread be certified to be pest-free prior to shipment.[67] Certification is conditioned upon the treatment of such stock, including soil treatment with chlordane, for the Japanese beetle and imported fire ant.[68]

Under the overall program is yet another program of a non-regulatory, cooperative nature, whereby quarantine area are designated and suppression and control efforts are instituted wherever necessary throughout the nation to prevent or control the movement of certain insects and pests.

One such effort has been directed over the years against the fire ant, under the auspices of the Federal-State Cooperative Imported Fire Ant Control Program. Between 1963 and 1967, the fire ant, characterized by its venomous sting and bit, spread through an area approximating 75 million acres. Largely due to action taken under the Federal-State control program, the area of additional spread between 1969 and 1973 was held to 3 million acres.

To illustrate the fire ant hazard, testimony adduced at the hearing reflects a tri-state (Mississippi, Alabama Georgia) survey of physicians, conducted in 1971, reporting upwards of 12,000 patients having been treated during a 6-9 month period for fire ant stings, which induced ap-

[67] USDA Ex. 8.

[68] Id. at 5.

proximately 6,000 allergic reactions, 6,000 secondary infections, 76 instances of anaphylactic shock, and resulted in 17 deaths.

Mirex, during the past decade, has replaced chlordane in the cooperative fire ant program. I note, however, the concern of the USDA over the future status and availability of mirex. On the assumption that chlordane will not be used for this purpose unless mirex is not available, and since no suitable alternative to those pesticides exists for use in the Cooperative Fire Ant Control Program, I will not suspend chlordane for this purpose.

As to the question of continued availability and use of chlordane upon nursery stock for the purpose of certification under the Japanese beetle and fire ant quarantine regulatory program, I am persuaded by the testimony submitted by the USDA that chlordane is the only effective and available larvacide to achieve this control, in light of USDA's evaluation of possible alternatives including carbaryl, malathion, methoryphlor, OMPA, Chlorpyrifos, resmethrin, allethrin, lindane, metesystox, ovex, diazinon, and rotenone.[69] None is reported as offering the necessary residual protection, while some are inactivated in the soil, leaving the larvae virtually unaffected. While certification may be accomplished by the dip or injection method of treatment with ethylene dibromide, this method is considered an emergency treatment until chlordane can be applied. This method is nearly prohibitive in cost and is time consuming, with a low incidence of plant survival.

The only treatment for sod, nursery stock with soil, and similar items accepted by the USDA for quarantine certification purposes are chlordane or chlordane in association with mirex. USDA Agricultural Research Service scientists who have screened alternative compounds find none effective for quarantine purposes.[70] Accordingly, I conclude

[69] USDA Exs. 6, 7, and 8.

[70] USDA Exs. 6, 7, and 8; Tr. 6008-09, 6141.

that continued use of chlordane is essential for effective quarantine of the Japanese beetle and the fire ant under the quarantine program.

3. *Imported Fire Ant*

The record of this proceeding suggests doubt concerning the ready availability of mirex and mirex baits for non-quarantine purposes, that is, for use by private individuals.[71] In consideration thereof, and in view of the public health problem which may result from the fire ant sting and bite (and the lack of any other effective and readily available alternative), I conclude that chlordane should be continued for use by individuals for this purpose.

4. *Black Vine Weevil in Michigan*

The State of Michigan's prohibition against the sale of nursery stock infested with black vine weevil is particularly applicable with respect to such infestations in the popular ornamental evergreen, the Japanese Yew.

The Michigan Agricultural Experiment Station recommends only chlordane for destruction of the black vine weevil larvae, which might otherwise infest and destroy the Yew root system.

A witness for the USDA testified that Yew nursery losses of $20,000 per acre could be forecast if chlordane were removed from the marketplace and the weevil left unchecked.[72]

In view of the fact that the affected area peculiarly subject to severe economic impact is small, that the amount of chlordane needed for effective treatment is relatively minor, and that no substitutes appear to be recommended or available, I conclude that the benefit of continued use of

[71] Tr. 6436-37.

[72] Tr. 6057.

chlordane exceeds the possible risk of harm which might result from its use for this purpose in Michigan.

5. *Harvester Ants*

Harvester ants are a significant public health concern, particularly in the arid Southwest. They inhabit large mounds which serve as a nest from which, when disturbed, they swarm to attack the source of disturbance. Their bite and sting frequently requires medical attention.

Heavy infestations of harvester ants also can cause erosion of soil, particularly roadside banks during periods of drought.

The only effective method of control known is through the use of baits treated with mirex or chlordane. It appears from the record that the harvester ant in Oklahoma (as distinguished from the Western harvester ant) is effectively controlled with chlordane bait, which may be due to somewhat different ecological conditions.[73]

The ALJ recommended that the use of chlordane bait be continued, but only in the State of Oklahoma.[74] Although I find such a geographical limitation somewhat puzzling in view of the fact that the subject pest is named the "Texas" harvester ant, I conclude that the record does not support extending this use beyond Oklahoma, as the ALJ recommended. With respect to that limited use, I conclude that the benefit of chlordane use for this purpose outweighs the possible risks.

6. *Household Garden, Lawn, and Turf Uses*

Chlordane is a commonly used house and garden insecticide. It is used in the home by homeowners and pest control operators to control both "non-structural" pests such

[73] Tr. 5812.

[74] Recommended Decision, p. 98.

as ants, cockroaches, spiders, crickets, earwigs, silverfish, firebrats, wasps, hornets, and other invading insects, as well as "structural" pests such as termites, carpenter ants, and "powder post beetles" (actually four groups of insects). Heptachlor generally is not recommended for use against household pests."[74]

Of a total of some 21 million pounds of chlordane used in the United States in 1974, about 7½ million pounds were devoted to home, garden, lawn, and turf use, or almost 36 percent to all chlordane used that year. The percentage used in home and garden, as distinquished from lawn and turf, is not apparent from the record.

a. *Non-structural Pests*

In the garden, chlordane is used as a soil treatment to control a wide variety of pests, including cutworms, maggots, wireworms, grubs, weevils, rootworms, and budworms. Its value for this purpose is due largely to its effectiveness and persistence for an entire growing season.

On the lawn, chlordane is used in granular form as a soil treatment to control a number of pests, including white grubs and ticks. Again, its principal value is its effectiveness and persistence.

In the home, chlordane is used against a variety of non-structural pests, including earwigs, crickets, centipedes, millipedes, spiders, silverfish, firebrats, wasps, carpenter ants, and hornets.

The registrant has stated that the importance of chlordane to the homeowner is indicated by the dollar figures on homeowner use of chlordane, which, according to one survey, accounted for about one-third of the gross sales of four of the largest home-use pesticide manufacturers, or almost 2.5 million pounds in 1974. Another estimate in the

[74] EPA Ex. 26-T, Table 1. See generally Velsicol's Brief on Benefits, pp. 35-53.

record is that homeowners spend about $50 million annually on chlordane for home use."[75]

The principal turf-damaging pests are the many species of white grubs (the larval stage of hard-shelled beetles) which feed on grass and plant roots. Both chlordane and heptachlor are valued for this use because of their residual effectiveness for several years. Chlordane is used as a soil treatment for turf around airports to control Japanese beetles, which seem to be peculiarly attracted to aircraft.

There is compelling testimony in the record that the benefits which result from the use of chlordane on the lawn, as well as in the home and garden, and the use of chlordane and heptachlor or turf, are considerably less than the risks associated with these uses, particularly in light of the availability of efficacious alternative pesticides.

Diazinon and dursban are effective alternatives for use on law and turf."[76] Diazinon, malathion, dursban, baygon, and DDVP are all effective against a wide variety of household and garden insects."[77] These and other insecticides are effective in controlling household roaches and ants, whereas the German cockroach (the most common household treatment by pesticide control operators) is resistant to chlordane."[78]

The risks to human intake associated with these uses of chlordane and heptachlor are manifest due to the many avenues which exist for direct exposure, through improper handling and misuse, inhalation, and absorption through the skin from direct contact."[79]

[75] Vel. Ex. 41, pp. 94-95.

[76] Tr. 5677.

[77] Tr. 5731-32, 5740, 5642, 5663, 5672-76.

[78] Tr. 4607.

[79] Tr. 4561.

For these reasons, including most importantly the availability of effective, economical alternatives and the high risk of direct exposure, I agree with the ALJ's recommendation that the continued use of heptachlor and chlordane for home, garden, lawn, and turf use not be permitted.

b. *Structural Pests*

In addition to the household pests discussed above, there are at least two significant household pests which cause structural damage to wooden floors, walls, and attic members. The "powder post beetle" and the carpenter ant can cause significant structural damage if not controlled.[81]

As with the other household uses discussed above, Judge Perlman found that adequate substitutes are available and effective for treatment against these wood-destroying insects. Lindane and pentachlorophenol are registered and recommended for powder post beetles.[82] Fumigation also is a possible alternative where surface treatments are not adequate, although there are some disadvantages in terms of acute toxicity (if improperly applied) and additional cost. Alternatives for treating carpenter ants also are available, including pyrethrins, DDVP, malathion, lindane, baygon, and diazinon.[83]

In view of the increased risk of direct exposure to chlordane when used in treating these household pests, I cannot conclude that the benefits of its use for this purpose are greater than the associated risks, particularly in light of the availability of effective substitutes.

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[81] The July 29, 1975, notice of intention to suspend specifically exempted the use of heptachlor or chlordane in subsurface ground injection for termite control from this suspension proceeding. (O.C.F.R. 34456).

[82] Tr. 7649-52.

[83] Tr. 4631-34.

c. *Agricultural Uses*

The dominant agricultural uses of chlordane and heptachlor subject to this proceeding include their use as soil treatment to control pests associated with corn, citrus, peanuts, pineapples, strawberries, and certain fruits and vegetables (registered for use on some forty varieties, including potatoes, tomatoes, cabbage, and grapes) and other miscellaneous crops, as well as seed dressing for corn, sorghum, and small grain seeds.

In the event of suspension, the ALJ recommended that, with the exception of use on corn (and on certain unspecified fruits and vegetables and other miscellaneous crops, as to which the record was insufficient to make any specific recommendation), all the above agricultural uses of heptachlor and chlordane be permitted to continue during the period required to complete the cancellation proceeding. That is, he recommended that heptachlor use for seed treatment and for control of the pineapple mealybug [84] not be suspended, and that chlordane use for control of the white-fringed beetle on peanuts,[85] control of the Fuller Rose Beetle and other root weevils on citrus,[86] as a preplant soil treatment in strawberry beds, and for control of white grubs in the State of Michigan [87] also not be suspended.

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[84] The ALJ's recommendation regarding use on pineapples is made subject to the proviso that should mirex be available for this purpose, after the conclusion of the mirex 6(b)(2) proceeding, this suspension proceeding could be reopened to reconsider the use of heptachlor for this purpose.

[85] The ALJ recommended that chlordane not be allowed for use to control the white-fringed beetle on tobacco.

[86] The ALJ recommended that the use of chlordane for controlling termites in the planting of new citrus trees not be continued.

[87] The problem of white grubs in Michigan relates principally to soy beans, dry beans, and small grains. The ALJ found no basis

Two actions taken by the parties late in the course of this suspension proceeding with regard to the agricultural uses of chlordane and heptachlor also must be taken into account. On November 25, 1975, the registrant submitted a letter regarding a voluntary curtailment of domestic shipments of heptachlor, in which it stated:

> As of November 24, 1975, Velsicol Chemical Corporation has voluntarily restricted domestic shipments of heptachlor to use for *termites* until a decision is reached by the Administrator regarding suspension. Should the Administrator find in favor of the continued use of heptachlor during a cancellation proceeding, Velsicol shall, nevertheless, voluntarily restrict domestic shipments of heptachlor to uses for termites, *seed treatment, fire ants* and *pineapples* pending completion of that proceeding. (emphasis added).

The effect of the registrant's commitment is a voluntary suspension of the use of heptachlor on corn and by pesticide control operators (*i.e.* on household pests, other than termites), which together constituted almost 85 percent of the heptachlor used in 1974. The other significant aspect of the registrant's commitment, is an obviously strong statement of its belief that the use of heptachlor on pineapples and for seed dressing (as well as fire ants) is necessary during 1976. These uses constituted most of the remaining 15 percent of the heptachlor used in 1974.

The second action referred to above concerns a statement made by the respondent, in its Exceptions to the Recommended Decision of the Presiding Officer filed on December 16, 1975, as follows:

> We do not contest dismissal of the suspension notice as to the following uses which should be more fully considered in cancellation and with respect to which the ALJ found that there are no adequate substitutes:[88]

in the record to extend the use of chlordane for this purpose beyond the State of Michigan.

Following the above statement is a listing of various uses of heptachlor and chlordane, including the following agricultural uses.

Heptachlor: — seed treatment
— pineapples

Chlordane: — Black vine weevil and white grubs in Michigan
— strawberries
— White fringed beetles in the eight Southern States (other than on tobacco)
— Florida citrus soil insects[89]

The effect of the respondent's statement is a voluntary agreement not to pursue suspension of the foregoing uses of heptachlor and chlordane. Of particular significance is the fact that respondent apparently concedes the need, at least during 1976, for the use of heptachlor on pineapples and for seed dressing. Also significant, however, is respondent's concession that all agricultural uses of chlordane at issue in this proceeding, other than on corn, should not be suspended. I must also assume from the respondent's exceptions that, although not specifically mentioned one way or the other, it does not contest the ALJ's recommended disposition of "certain fruits and vegetables and other miscellaneous crops", as to which he concluded that the record was "too general, imprecise and inadequate and the evidence is too conflicting and uncertain . . . to enable us to form a judgment . . . ."

[88] Respondent's Exceptions to the Presiding Officer's Recommended Decision, p. 4.

[89] I b d.

In view of the ALJ's recommendations and the actions taken by the registrant and the respondent, I am tempted to conclude summarily that the question of suspension as to all agricultural uses of heptachlor and chlordane (except the use on corn) can be resolved (in favor of continued use) without any extended consideration of the relative risks and benefits associated with each specific use. In spite of the foregoing, I feel compelled to state my understanding and assessment of the risks and benefits of each of these uses.

1. *Hawaiian Pineapples*

Heptachlor is employed by Hawaiian pineapple growers to control ants, and thereby control the spread of mealy bug wilt. This disease arises out of a virus in the pineapple plant which is activated by the saliva of the feeding mealy bug. The mealy bug depends for transport from plant to plant and for survival upon the ant which feeds upon the sweet tasting exudate of the bug, which but for this removal would drown or suffocate in the exulate. Effective ant control, therefore, is essential to the control of the mealy bug wilt. This has been generally and successfully effected by the use of mirex baits. Mirex bait has generally replaced the earlier method of control through heptachlor soil treatments. To the limited extent that these baits are rendered ineffective by the excessive rainfall, foliar applications of heptachlor are made upon the matured plant.

Diazinon and malathion, as alternative foliar applications, are considered ineffective against subterranean infestation. Mealy bugs, as distinguished from ants, can be partially controlled by these pesticides. Were these the only factors to be considered, the case for continued availability of heptachlor for mealy bug wilt control would lack strong basis. However, a serious question exists regarding the safety of mirex which is presently being examined in

an ongoing hearing under Section 6(b)(2) of FIFRA. As a result, there is some doubt cast upon the continued availability of mirex baits, as evidenced by a letter received late in the mirex hearing from the chemical manufacturer of the bait, representing that production of these baits has ceased as of July 1975, with no present manufacturer intention to resume that production.

The record clearly reveals that heptachlor is used on pineapples in minimal amounts within prescribed boundaries, under close professional supervision, and at infrequent intervals. In addition, a zero tolerance exists for residues of heptachlor on raw pineapples. Annual use of heptachlor for the Hawaiian pineapple crop is projected at only 7700 pounds, subject to the continued availability of mirex and the findings and recommendations which may emerge from the hearing bearing upon its safety.

While it is undisputed that mealy bug wilt is under control, this factor obviously does not eliminate the need to continue certain agricultural practices which appear to have achieved this condition. Indeed, this fact militates toward continuance of such practices.

In view of the uncertainties involving the availability of mirex, the fact that at the present time the amount of heptachlor used is very small, and the fact that existing alternative chemicals lack efficacy as substitutes, I must conclude that the benefits attendant upon the use of heptachlor outweigh any risks associated with its use on pineapples during the period required to complete the cancellation proceeding.

2. *Seed Treatment*

Heptachlor treatment or dressing of seed, particularly that of corn, sorghum, and certain small grains, provides effective control at minimal cost to the farmer of insects which attack and otherwise feed upon the seed. Most nota-

ble among these insects are the seed corn beetles and maggots and wireworms.

The high residual and persistent nature of heptachlor protects the seed for extended periods while stored and during the post-planting period through germination. Alternate chemicals registered for seed treatment are diazinon and lindane. The record reflects considerable misgivings concerning the persistency level of diazinon and the degree of protection it provides the seed, particularly against the wireworm. Present lack of efficacy and phytotoxicity data casts additional doubt upon diazinon's merits as a reasonable alternative to heptachlor.

Nor, for the purpose of this proceeding, can lindane qualify as a viable, available, and realistic alternative. The evidence is uncontroverted that lindane is presently, and is expected to remain for an indeterminate period, in low production and short supply pending the outcome of examination and testing which bear upon its safety. This totality distinguishes these facts from the issue raised in the aldrin-dieldrin cancellation proceeding reflecting the utility of heptachlor as an alternative seed treatment to dieldrin. I therefore find it unnecessary to adjudicate the conflicting claims revealed in testimony at the instant Hearing bearing upon whether lindane would *otherwise* qualify as an adequate seed treatment alternative to heptachlor.

No other alternatives proposed, including pyrethrins and malathion, appear to provide protection against seed attacking soil insects. In a similar category is methorychlor, which is used for the limited purpose of stored product insect control.

I conclude, therefore, that there is a continuing need by the farmers for commercial seed treatment, particularly for use in the Southwest, as well as other seed treatment, including planter box treatment, in other parts of the country, and that this need outweighs any risks associated

with the use of heptachlor for this purpose during the period required to complete the cancellation proceeding.

3. *White Fringed Beetle*

This pest has so persisted in the States of Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee since it was first detected ravaging peanut crops in the 1930's that, until recently, it was the subject of a Federal quarantine program for 3½ decades.

It is during the early larval stage that most of the crop destruction occurs, as the larvae feed upon the plant roots. They migrate through the soil at depths of 4-6 inches.[90]

Incorporation of chlordane several inches into the soil prior to planting appears to be the most effective treatment for larvae control. Due to the high residual character of chlordane, such treatment may be effective for 2-3 years.[91]

The registrant projects that of 20,000 acres and 26,000 acres in Alabama and Georgia, respectively, in which infestation is expected to occur during the 1975-76 growing season, only 15,000 acres (or 75 percent) and 13,000 acres (or 50 percent), respectively, in those states will be treated.[92] Without assessing the accuracy of this projection, suffice it to say that such a potential may be explained by the fact that insurance treatments do not typify the peanut grower's practice.[93] Rather, his treatment is predicated upon detection of the larvae, which is rendered difficult because of its small size in the earlier critical

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[90] Tr. 6208.

[91] Tr. 5867.

[92] Vel. Brief on Benefits, p. 167.

[93] Tr. 6322.

stages. Upon detection, only those portions of the field are treated in which the infestation has occurred.

While this practice appears to occasion considerable losses (estimated for the 1976-77 growing season by the registrant to exceed $1 million and $2 million in Alabama and Georgia, respectively), it certainly does not suggest overuse of chlordane, as perhaps insurance treatments might suggest.

The long persistence of the beetle in the Southern states merits concern, particularly since no alternative chemicals are registered for their treatment.

In view of the foregoing, I conclude that the continued availability of chlordane within the abovementioned eight Southern states is necessary for the control of the white fringed beetle infestations in food crops grown in those states. I conclude otherwise with respect to the tobacco crop use, since the record discloses that a diazinon treatment is equally effective as chlordane (although for a shorter period of time) and that it is available for pesticidal treatment of tobacco.[94]

4. *Florida Citrus Soil Insects*

Chlordane is used as a soil insecticide to control the Florida citrus weevil complex, particularly the Fuller's Rose Beetle or weevil. This method of control is primarily centered in the Indian River region of Florida, one of two prominent citrus regions in the state. The geology of that area permits only a shallow rooting system which increases the citrus tree's susceptibility to attack by the root-feeding weevil larvae,[95] with consequent results of sparse foliage, poor fruit yields, stunted growth, and destruction of infested younger trees.[96]

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[94] Tr. 6223, 6297, 6322, 6347.

[95] Tr. 4830.

[96] Tr. 4794; EPA Ex. 26-N, p. 4.

Control of the weevil is accomplished as the weevils pass through the treated soil in completion of their life cycle from larvae to adults. Without the benefits of soil insecticide in infested areas, the weevil emerges from the soil as an adult and must be contained by the use of foliar sprays. Foliar applications, however, apparently kill predators and parasites, such as the wasp, which is relied upon to control scales and mites, which themselves are extremely serious pests to Florida citrus crops.[97]

Florida has implemented an integrated pest control program for citrus which combines biological and chemical control methods, and results in reduced pesticide use.[98]

The hearing record indicates that two species of wasps were introduced within the past decade to control red and purple scales, which were then among the most significant pests. Introduction of the wasps reduced the foliar applications of chemicals from as many as eight to one or two annually.

Based upon experimental data submitted with Velsicol's Exhibit 16, a witness for the registrant concluded that there were a number of promising materials for the control of the Fuller Rose Beetle.[99] The witness explained, however, that due to the grower reluctance to participate in any experimental tests with alternative compounds, no test data has been generated since 1971. In view of this, I join with the ALJ in urging the Florida citrus industry to re-commence this research at the earliest possible date.

Considering the economic impact which could result to the Florida citrus industry without the benefit of an effective soil insecticide, and recognizing that chlordane is supplied at intervals and in quantities which minimize the pos-

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[97] Tr. 4879.

[98] Tr. 4728-29.

[99] Tr. 4791-92.

sible risks due to this use, I conclude that chlordane use to control Florida citrus soil insects should continue.

5. *Strawberries*

Chlordane is specifically recommended as a preplant soil treatment for strawberries grown in Minnesota, Michigan, Ohio, New York, Connecticut, Massachusetts, Maine, Vermont, New Jersey, Maryland, and West Virginia, because of its highly persistent quality which protects the plant against root destroying insects for 4-6 years.[100] This extended protection appears especially necessary and desirable since a strawberry plant may be expected to produce (after the first year) annual crops up to the sixth year after initial fruiting.

The economics of a strawberry grower's decision as to when a plant should be ploughed under and a new crop planted appears to depend largely upon the type of growing operation involved. Larger growers, particularly those in California, customarily re-fruit the beds annually, and therefore do not generally employ the persistent chlordane preplant treatment.[101] This practice contrasts with that found particularly in the Northeastern states, in which strawberry farming is typically a smaller operation and strawberry beds are fruited for a 4-6 year crop.

Proposed alternative chemicals such as diazinon and carbaryl are not registered at sufficiently high rates of application to provide effective control. Other chemical alternatives are effective only as to some soil insects or are efficacious as foliar sprays applied frequently. The success of fumigants (extensively used in California) depends upon sufficiently high soil temperatures, which creates a

[100] Tr. 5457-58.

[101] Approximately 16-20 percent of the total California strawberry acreage was treated with chlordane in 1974. Tr. 5464.

problem in the Northern and Northeastern strawberry growing states.[102]

While the more significant portion of strawberry plant acreage in the United States would be relatively unaffected by a chlordane suspension, the record indicates such a suspension would result in a significant adverse impact upon smaller strawberry growers in those states in which the chlordane preplant treatment appears necessary.[103] Moreover, the amount of chlordane involved for this purpose is quite small.[104]

When measured against the possible risks associated with the continued use of chlordane on strawberries, the economic desirability for continued use of chlordane for preplant treatments appears more compelling at this time.

6. *White Grubs in the State of Michigan*

White grubs (of which there are many species) appear to be a problem of special significance in the Lower Peninsula of Michigan. Grubs feed on the roots of any crop planted in the field, which weakens the plant and reduces crop yield.

While the estimated cropland in Michigan annually infested with the white grub aggregates only some 20,000 acres, serious economic plight is forecast for farmers deprived of an effective and economically feasible means of grub control. Chlordane treatments are not recommended unless the grubs are actually detected in the fields. The amount of chlordane involved in this use is small.

An alternative to chemical control, *viz.*, clean fallow for one year, does not appear to be an economically viable alternative.[105]

[102] Tr. 5504.

[103] Tr. 2825.

[104] Tr. 2826.

[105] USDA Ex. 10, p. 4.

In view of the record in this matter, I believe the benefits of continued availability of chlordane during 1976 for this limited purpose in Michigan outweighs the possible risks associated with its use.

7. *Corn*

The ALJ characterized the use of heptachlor or chlordane to control cutworms in corn crops as "the single most difficult issue in the risk-benefit analysis."[106] That assessment is due, in part at least, to the fact that is represents the major use of heptachlor and the major agricultural use of chlordane. During 1974, the combined use of heptachlor and chlordane on corn accounted for about 5.5 million pounds (or slightly less than 25 percent) of the total amount of 23.23 million pounds of chlordane and heptachlor used during that year.

Of the some 6 million pounds of chlordane used in agriculture generally during 1974, data submitted by the registrant indicates that 4.32 million pounds were used on corn. As of 1975, chlordane is used on about 1.2 million acres of corn, or some 1.6 percent of the total U.S. corn acreage. This includes about 12,000 farms, or 1.3 percent of all U.S. commercial corn farms.

Of a total volume of 2.05 million pounds of heptachlor used during 1974 (about three-fourths of which was devoted to agriculture), data submitted by the registrant indicates that 1.19 million pounds were used on corn. As of 1975, heptachlor is used on about 1.4 million acres of corn, or some 1.9 percent of the total U.S. corn acreage. This includes about 15,500 farms, or 1.7 percent of all U.S. commercial corn farms.

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[106] Recommended Decision, p. 104.

The ALJ, citing data submitted by the registrant, found that use on corn constituted 58% of the total use of heptachlor during 1974 and 20.4% of the total use of chlordane for that year. Recommended Decision, pp. 20, 22.

Thus, chlordane and heptachlor together are used on about 2.6 million acres of corn as of 1975, or some 3.5 percent of the total U.S. corn acreage. They are used on some 27,500 farms, equalling about 3 percent of all commercial corn farms in the United States.

Comparisons between 1974 and 1975 statistics suggest that some of the increase in heptachlor and chlordane use in 1975 (up from 1.3 percent in 1974 to 1.6 percent in 1975 of total U.S. corn acreage in the case of chlordane, and up from 1.2 percent to 1.9 percent in the case of heptachlor) is due to the decline in use of aldrin (from 9.6 percent in 1973/74 to 3.3 percent in 1975) following the suspension of aldrin prior to the 1975 growing season.

An additional important factor concerning the corn use issue is the matter of its efficacy in controlling certain corn pests. Rootworms, wireworms, and cutworms are the dominant corn pests for which chlordane and heptachlor and other chlorinated hydrocarbon soil treatments have been recommended in the past. Chlordane and/or heptachlor have registrations for use against these and other lesser economic corn pests. It is clear from the record, however, as reflected in the ALJ's recommendations, that the dominant concern centers on the black cutworm. It appears that the registrant has not argued for the use of heptachlor/chlordane on corn rootworms because of developed resistance.[107] It also appears that wireworms did not constitute a significant issue in controversy at the hearing, due largely to the availability of adequate substitute chemicals, nonchemical control methods (rotation), and resistance.[108] Thus, the real issue in this proceeding, insofar as corn use is concerned, is the need for heptachlor/chlordane to control cutworms.

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[107] Recommended Decision, p. 104 n. 38.

[108] Recommended Decision, p. 104 n. 38.

The record indicates that the highest risk of cutworm infestation occurs in lowland, river bottom areas, such as the Missouri River bottom areas in Missouri. In these fields, damaging infestations generally occur one out of three years or two out of five years. Estimates of the numbers of high risk acres treated for cutworm infestations include 900,000 acres (or about 30 percent) of Missouri corn land and some 450,000 acres (or about 12 percent) in Ohio. These figures represent the acres treated, and not necessarily the acres known to be actually infested.

During the period 1969 to 1975, the number of farms reporting cutworms as a *major problem* varied from 19,000 to 71,000 (2 to 8 percent of total U.S. corn farms), with an overall average of some 53,000 farms. During the same period, the number of farms *treating* for cutworms ranged from 13,000 to 48,000 (52 to 71 percent of those reporting a major cutworm problem), with an overall average of about 32,000 farms. This illustrates the highly variable nature of cutworm infestations (and treatment) and the concommitant difficulty of projecting economic thresholds for treatment.

It is difficult to judge from these statistics or from more general statements in the record what the actual need may be for our corn soil treatments with heptachlor or chlordane. It is significant that the States of Illinois and Iowa do not recommend any chlorinated hydrocarbons as a preplant soil incorporation insecticide for control of the cutworm. Yet, many farmers in the eight-state "Corn Belt" region have, or believe they have, a significant need for soil treatments with persistent pesticides. In 1975, Missouri corn farmers treated 30 percent of their commercial corn land with chlorinated hydrocarbons, while in Indiana 14.1 percent of the corn acreage was so treated, with lesser percentages for the other major corn growing states. The record indicates that while an average of only some 6 percent of U.S. corn farms reported major cutworm problems

during 1969 to 1975, in 1973 and 1974 chlorinated hydrocarbons were used on over 12 percent of all U.S. corn acres.

This statistic, together with other information, has given rise to the charge that corn farmers over the past several years have unnecessarily applied persistent pesticides on an "insurance" or "prophylactic" basis, without actual confirmation of significant economic levels of infestation. In the aldrin-dieldrin suspension decision last year, in fact, I determined that corn farmers had continued to use those pesticides even in the absence of an indication of an actual threat of economic injury.

The most difficult aspect of the corn use issue is the matter of projecting economic losses which might result from the absence of heptachlor and chlordane. The ALJ discussed at length the macroeconomic impact analyses of two entomologists who testified for the registrant, and characterized their estimates as "admittedly 'shaky'," uncorroborated, and disputed. He expressed some dismay at the lack of "detailed and specific evidence as to cutworm damage in the Corn Belt *at significant economic levels* if such injury caused significant yield losses." [109]

Given the difficulty of making macroeconomic impact projections (which is virtually conceded by all parties), it is nonetheless essential to make a judgment based on the limited information and opinion available in the record. The registrant's witness, Dr. Fairchild, estimated that nationwide losses to corn production if heptachlor and chlordane registrations are suspended could be in the range of two to five percent.[110] In some high risk, lowland areas (such as Missouri and Southern Illinois), he stated that the loss could be up to fifteen percent.[111] In his view, what-

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[109] Recommended Decision, p. 107.

[110] Vel. Ex. 34, p. 1.

[111] Vel. Ex. 34, p. 25.

ever the actual percentages, the overall loss would be "substantial and important." [112]

Dr. Musick, the second entomologist witness for the registrant, testified that the estimated nationwide loss would be in the range of two to three percent of the nation's corn crop.[113]

Studies conducted by the Stanford Research Institute for the registrant suggest that the "low range" economic impact for corn is $79.1 million and the "high range" is $673.75 million.[114]

In contrast to the foregoing estimates by the registrant, the respondent's evaluation of macroeconomic impacts, using the EPA agricultural lineal programming model and reflecting the results of two long-term productivity studies in Illinois and Iowa,[115] concluded that "the benefits of chlorinated hydrocarbon treatments for corn soil insects are generally in the range of 6-10% over acres receiving no treatment."

Two evaluations of the impacts of heptachlor and chlordane removal presented by Dr. Aspelin for the respondent concluded that in the "typical-year case," a slight increase in corn production (200,000 bushels) would result in 1977, and the price impact of suspension on corn would be nominal. In the "worst case," impacts would result in a reduction of corn production by 0.7 percent (or 37 million bushels) leading to price increases for corn of 2.6 percent. Dr. Aspelin predicated that the impact from suspension in the 1976 growing year would be somewhat less than the typical-case year, largely due to the availability of existing stocks of chlordane and heptachlor.

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[112] *Ibid.*

[113] Vel. Ex. 35, p. 22.

[114] Vel. Ex. 41, p. 19a.

[115] EPA Ex. 26-L, pp. 8-11.

The respondent also cited the general statements of entomologists contacted in the Stanford Research Institute study to the effect that there would be "no serious impact" (Iowa),[116] "essentially no impact" (Illinois),[117] "little effect" (Indiana),[118] and "not much of an impact statewide" (Ohio).[119]

The respondent, moreover, succeeded in pointing out a number of significant deficiencies in the registrant's loss estimates, citing in particular the failure to include in their estimates the availability of treatment alternatives and the use of existing stocks in 1976.

In considering the foregoing, as well as other information in the record, I agree with the ALJ's conclusion that the registrant has not established and significant macroeconomic effect from the suspension of heptachlor and chlordane in relation to corn production.

There is, however, another major consideration involving economic and social impact which I believe is more compelling than the foregoing analysis; namely, the likely impact of suspension of heptachlor and chlordane on the high cutworm risk corn-producing areas and on individual farmers within those regions and elsewhere. The ALJ expressed his concern and "agony" over the possible effect of suspension upon certain individual farmers. He acknowledged that in certain limited areas of the Corn Belt a "very real threat" exists from the cutworm. He was persuaded, however, that mitigating factors (alternative preplant or post-emergent treatment and/or replanting) would reduce the potential loss to these farmers, even though he was obviously troubled by a "nagging fear" that the af-

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[116] Tr. 8122.

[117] Tr. 8183.

[118] Tr. 8125.

[119] Tr. 8126.

fected corn farmers might not be willing to change or adjust to the different techniques required for post-emergent treatment with baits and sprays.

The difficulty in assessing this microeconomic impact issue is the lack of hard information in the record. Yet, it is apparent that as many as 27,000 farmers (out of the nation's 900,000-plus farms) are likely to be significantly penalized by the removal of heptachlor and chlordane. The question to be asked is whether this projected cost is justified in view of the nature and magnitude of the risks associated with the use of heptachlor and chlordane on corn.

As noted above, the ALJ agonized over the problems which suspension would present to the individual corn farmer of Missouri bottomland and concluded that they would be "substantial." But, he was equally concerned with "the application of millions of pounds of the pesticides involved and [we] know of no way to define limitations on use to cover only very essential cases since much of the applications of heptachlor and chlordane are for 'insurance' purposes . . ." [120]

The ALJ's concern about the amount of the pesticides to be applied may be mitigated to some extent by the registrant's decision to voluntarily to restrict domestic shipments of heptachlor for use on corn, but, as the ALJ also found, "it appears that chlordane production is capable of replacing any heptachlor eliminated by the offer of commitment [of the registrant]." [121]

In 1974, some 1.19 million pounds of heptachlor was used on corn. Presumably, even if suspended, some existing stocks of heptachlor will be available for use on corn during the 1976 growing season, but no doubt at a reduced amount

[120] Recommended Decision, p. 109.

[121] Recommended Decision, p. 104.

compared to 1974. Some 4.32 million pounds of chlordane was used on corn in 1974. With the suspension of aldrin-dieldrin in 1974, the amount of heptachlor and chlordane used on corn in 1975 has probably increased, although the record does not contain a poundage figure for 1975 use. If applied at the rate of 2 pounds per acre, however, it appears that the 3.5 million acres of heptachlor/chlordane used on corn in 1975 would mean that approximately 7 million pounds were used in 1975, which is about 1.5 million pounds more than the 1974 level.

The essential question to be resolved is whether the introduction of some 7 million pounds of chlordane (assuming a one-for-one substitution of chlordane for heptachlor) into the environment through its use on corn represents an unreasonable risk in view of the conclusion reached herein that there is a substantial likelihood that serious harm will be experienced from the continued use of heptachlor and chlordane. I conclude that the risks associated with this use do not constitute an unreasonable risk to man or the environment such that it should be suspended *for the 1976 growing season*. During the more than one year before the 1977 growing season begins, I urge the USDA and the affected States to engage in the educational programs necessary to inform farmers of the alternative techniques necessary to avoid the use of chlordane, in the event that the cancellation proceeding lasts into the 1977 season. This education will, of course, also prove valuable if the final decision of the cancellation proceeding is the permanent removal of chlordane from the market for this use, but in any event it will be worthwhile for the purpose of stopping the bad practice of making needless "insurance" applications of this persistent pesticide.

The combined effect of the actions described herein (suspension of chlordane for all home, garden, lawn, and turf uses (including PCO use), as well as suspension of heptachlor use by PCO's and the registrant's voluntary

suspension of heptachlor use of corn) means that the total amount of heptachlor and chlordane introduced into the environment during the period required to complete the cancellation proceeding will be greatly reduced from 1974 levels. Using 1974 data, it appears that the amount of chlordane eliminated from the environment by these actions will constitute roughly a *70 percent* reduction from the 1974 total amount of *chlordane* used (*i.e.*, 29.9 percent for home, lawn, and garden; 5.9 percent for turf; and 34.7 percent by PCO's). These actions (including the registrant's commitment regarding the suspension of domestic shipments of heptachlor for use on corn) also mean that almost 85 percent of the 1974 total amount of heptachlor used (*i.e.*, 58 percent on corn; 26.8 percent by PCO's) will be eliminated from the environment during 1976. These figures are somewhat inflated, obviously, since some existing stocks will be available for use during 1976, although the exact amount cannot now be determined.

A considerable part of the record of this proceeding dealing with the implications of a suspension of chlordane treatment on corn crops concerns a discussion of the impact that suspension would have upon the Missouri bottomland farmer, inasmuch as 30 percent of the corn acreage in that state is treated with chlorinated hydrocarbons.

A witness for the registrant from Missouri was examined at length during the hearing upon his view that no reasonable alternative to chlordane exists, despite the fact that (as well as chlordane) diazinon is recommended by the State of Missouri in the official State Insecticide Recommendations for 1975, for use as a preplant treatment on corn.[122] The witness' explanation was that diazinon, to be effective against the curworm, would have to be applied

[122] EPA Ex. 26G. Indiana and Nebraska make the same recommendation. The States of Michigan, and South Dakota recommend diazinon as a band treatment. Michigan also recommends diazinon as a foliar spray.

immediately prior to planting in view of its lower residual character when compared with chlordane. He agreed, however, that diazinon "greatly reduced the cutworm population." [123]

The testimony of record also reveals that the most destructive cutworm population is that which hits the corn plant after the growing plant has emerged from the ground, and that this occurs, under ideal warm conditions, about three weeks after planting.[124] It is at about this time that cutworm damage is detectable.

To the extent that preplant soil treatment is not effective, post-emergent treatment or, if the damage is too extensive, replanting may be necessary. According to a study conducted in 1971-1972, 3.61 percent of pretreatment corn acreage in Missouri had to be replanted because of extensive cutworm damage.[125] This occurred despite the presumed use of aldrin or chlordane.

Post-emergent sprays and baits are recommended in Corn Belt states either as auxiliary methods of controlling the cutworm following preplant treatment, or in lieu thereof.[126] The two largest corn producing states in the nation, Iowa and Illinois, recommend carbaryl baits and sprays in lieu of pretreatment. Indiana, Iowa, Minnesota, Missouri, Ohio and South Dakota also recommend carbaryl as a post-emergent treatment.[127] Toxaphene spray is recommended in all Corn Belt states except Illinois. Dylox baits are recommended in Illinois, Indiana, and Kansas. Dylox spray is recommended in all Corn Belt states.

[123] Tr. 6976.

[124] Tr. 6979.

[125] Tr. 7027.

[126] Tr. 6909.

[127] EPA Ex. 26-G.

I am well aware, after close examination of the record, of the many problems associated with crop surveillance or "scouting," and I do not minimize their significance. Missouri has had a scouting program on cotton since the late 1950's and it has proved to be a "very successfull program." [128] That scouting for corn pests has not received the same priority that cotton scouting programs have received in the past may be explained by the availability of inexpensive chlorinated hydrocarbon insecticides during the past two decades. Yet, I note that scouting programs are currently sponsored by state entomology departments throughout the Corn Belt.[129]

Also noteworthy is the statement of a witness as follows:

> We have been telling the farmer for many years to go out and check his fields. He inherently has not been doing that. For whatever the reason, he does not do it. Also, he will tell you he is checking his fields when in effect all he is doing is driving by the field and glancing out over the edge of it. He doesn't recognize damage until a significant number of plants are gone. He isn't out there doing what we asked him to do.[130]

I can only conclude from the foregoing that even the most persistent preplant treatment on corn provides no panacea to the problem with cutworms. Rather, the record most persuasively suggests that this problem would become one of degree following a suspension of the use of chlordane, and that it is a problem which a more concerted effort at crop surveillance could, to the largest extent, remedy.

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[128] Tr. 7018.

[129] Tr. 7015.

[130] Tr. 7209-7210.

Nonetheless, I am also persuaded that, at least with respect to the 1976 growing season, a significantly large number of individual corn farmers in high cutworm risk areas will not be able to make a satisfactory transition to effective post-emergent treatment programs, and thus find that there is a continuing need during the 1976 planting season for chlordane.

I am convinced, however, that the overall reduction in the total amount of heptachlor and chlordane to be introduced into the environment in 1976 as a result of this proceeding means that the risk to man and the environment will be significantly reduced and that this result represents a reasonable balancing of the relative risks and benefits.

However, in order to insure that even the reduced degree of risk assumed by this Decision is not prolonged by the possibility that the cancellation proceeding may carry over into the 1977 corn growing season, I have concluded that the volume of chlordane used on corn which may be anticipated during the 1976 growing season (based on the 1974/1975 corn use figures and estimates of 7 million pounds) is such that it should not be continued beyond the 1976 growing season, regardless of when the cancellation proceeding is completed.

For all of the foregoing reasons, I have determined that the use of heptachlor and chlordane on corn should be suspended; provided, however, that such suspension shall not become effective until August 1, 1976.

IV. Conclusions

1. Based on the testimony of record in the suspension hearing and the considerations set forth in Part II of this Decision, I have concluded that the continued use of heptachlor and chlordane during the time required to reach a final decision in the cancellation proceeding presents a substantial likelihood that serious harm to man or the environ-

ment will be experienced during that period. I also conclude, based on the record of the hearing and taking into account the economic, social, and environmental costs and benefits of the use of heptachlor and chlordane, that the continued use of heptachlor and chlordane during the time required to reach a final decision in the cancellation proceeding would be likely to result in an unreasonable human health risk and, therefore, than an "imminent hazard" within the meaning of section 2(1) of FIFRA would result during the pendency of the cancellation proceeding.

2. I have concluded further, based on the testimony or record and the considerations set forth with respect thereto in Part III of this Decision, that the benefits of continued use of heptachlor and chlordane for household, garden, lawn, and turf purposes (both by private homeowners and by pesticide control operators), against ticks and chiggers, and as a constituent in shelf paper, during the time required to reach a final decision in the cancellation proceeding, are not sufficient to outweigh the human health risks identified, and that, in any event, alternative registered and recommended pesticides do exist and will be available to provide effective, economical pest control for these purposes.

3. I have concluded further, based on the testimony of record and the considerations set forth with respect thereto in Part III of this Decision, that the benefits of continued use of heptachlor and chlordane to control cutworms on corn crops during the time which may be required to reach a final decision in the cancellation proceeding are not sufficient to outweigh the human health risks identified; *provided, however,* that particularly in view of the difficult transition required to implement alternative cutworm control methods, the use of heptachlor and chlordane to control cutworm on corn crops should be permitted during the 1976 corn growing season. Accordingly, I have concluded that the registration for use of heptachlor and

chlordane to control cutworms on corn crops should be suspended effective August , 1976.

4. Notwithstanding the foregoing conclusion regarding the existence of an "imminent hazard," I have concluded that the benefits of continued use of heptachlor for control of the (1) narcissus bulb fly, (2) seed treatment, and (3) the pineapple mealybug, and the continued use of chlordane for the (1) Federal-State quarantine programs for Japanese beetle and imported fire ant, (2) the Michigan quarantine program for black vine weevil, (3) the harvester ant (in Oklahoma), (4) the imported fire ant, (5) the white fringed beetle (except on tobacco), (6) the Fuller Rose Beetle and other root weevils on Florida citrus crops, (7) the root-destroying pests on strawberry crops, and (8) white grubs in the State of Michigan, during the time required to reach a final decision in the cancellation proceeding outweigh the human health risks identified, particularly in view of the unavailability and cost of alternative treatment methods and the relatively small amounts of heptachlor or chlordane used for these purposes.

5. It should be noted that the record in this proceeding is not sufficient to reach a conclusion regarding the continued use of heptachlor or chlordane on certain fruits and vegetables and other miscellaneous crops. Further evidence should be forthcoming in the cancellation proceeding to resolve the question of cancellation with respect to these uses.

6. The effect of this decision is greatly to restrict the amount of heptachlor and chlordane which will be introduced into the environment during the time required to reach a final decision in the cancellation proceeding. The suspension of heptachlor use for household, garden, lawn, and turf purposes, together with the registrant's voluntary commitment to restrict domestic shipments of heptachlor to uses for termites, seed treatment, fire ants, and pineapples pending completion of the cancellation proceeding

(*i.e.*, most significantly, eliminating its use on corn), means that the amount of heptachlor will be reduced (by comparison to 1974 use levels) by almost 85 percent. Moreover, the amount of chlordane will be reduced (by comparison to 1974 use levels) by more than 70 percent immediately and, after August 1, 1976 (the effective date for suspension of chlordane use on corn crops), by over 90 percent.

While these reductions are the best estimates which can now be made, it should be noted that some additional heptachlor and chlordane will be available during 197 from existing stocks. As set forth in the notice of intention to suspend issued on July 29, 1975, the continued use of stocks of heptachlor and chlordane in existence as of that date will be permitted. Although the precise amount of existing stocks was not determined in the suspension hearing, it was clear that at the time the notice of intent to suspend was issued that the continued use of these stocks would be environmentally safer than attempting to retrieve them, transport them, and then somehow dispose of the consolidated and remaining supplies. I also do not think it would be appropriate to penalize farmers, growers, and other users who have already purchased these pesticides with the expectation of being able to use them.

/s/ Russell E. Train

December 24, 1975

United States of America
Environmental Protection Agency
Before the Administrator

FIFRA Docket No. 384

In re
Velsicol Chemical Corporation et al., *Registrants.*

Order

In accordance with the foregoing Decision, the registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. § 135, *et seq.*, for all pesticide products containing heptachlor or chlordane for use (1) on corn pests, (2) on household, garden, lawn, and turf pests (both by private homeowners and by pesticide control operators), (3) against ticks and chiggers, and (4) as a constituent in shelf paper, are hereby suspended and the production of all such pesticide products intended for the foregoing uses is prohibited; *provided, however,* that this suspension and prohibition as to products for use on corn pests shall not become effective until August 1, 1976. Any stocks of technical grade heptachlor or chlordane formulated into products intended for such uses after July 29, 1975, may not be placed in commerce, sold, or used for such purposes or any other purpose not specifically exempted in the November 18, 1974, cancellation order or specifically permitted in accordance with the Decision of the Administrator attached hereto.

Notwithstanding the foregoing, for the reasons stated in my Notice of Intention to Suspend dated July 29, 1975, and in accordance with the "Special Rule" provisions of section 15(b)(2) of FIFRA, the continued sale and use of existing stocks of registered products containing heptachlor or chlordane which were formulated prior to July 29, 1975, shall be permitted.

/s/ Russell E. Train

Dated: December 24, 1975

UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

FIFRA Docket No. 384

In Re:

VELSICOL CHEMICAL CORPORATION ET AL., *Registrants.*

Clarification of Order of December 24, 1975

On January 7, 1975, Respondent EPA filed a Suggestion for Clarification of the Order of December 24, 1975, in the above-captioned proceeding, seeking clarification of the uses of products containing heptachlor and chlordane for which registrations are *not* suspended by the December 24 Decision and Order. Respondent also submitted a Proposed Order, including an attachment setting forth a proposed list of uses not suspended, together with certain explanatory notes.

On January 13, 1976, I issued a notice of the filing of Respondent's Suggestion for Clarification and Proposed Order and requested written comments from the parties, thereby indicating my intention to consider the possible need for clarification of the December 24 Decision and Order.* On January 15, 1976, written comments were received from counsel for Velsicol Chemical Corporation; counsel for the Pineapple Growers Association of Hawaii and the Attorney General and Department of Agriculture of the State of Hawaii; counsel for some 300 registrants of various products containing heptachlor or chlordane; the Environmental Defense Fund; the U.S. Department of

* Written comments in response to Respondent's suggested clarification were submitted by counsel for Velsicol Chemical Corporation on January 12, 1976, but not sufficiently in advance of the preparation of the January 13 notice to be considered therein.

Agriculture; and Respondent EPA. All of the foregoing parties, except the Environmental Defense Fund, oppose Respondent's suggested clarification of the December 24 Order, both on grounds that the Administrator lacks jurisdiction or authority to clarify, modify, or alter the Order and that the Order is final and cannot now be changed in the manner proposed by Respondent.

Even though not expressly provided for in the Rules of Practice governing expedited hearings under the FIFRA, I have determined that authority does exist to clarify the December 24 Order and that some clarification is warranted, in view of the apparent possibility that its provisions may be unclear. In my view, the December 24 Decision and Order are clear and specific in their terms and should not require any further elaboration. Implicit in Respondent's suggested clarification, however, is the notion that proper administration of the Decision and Order by the Agency and explicit understanding thereof by all the parties require a clear statement of the uses of products containing heptachlor and chlordane for which registrations have not been suspended. In an abundance of caution and concern, therefore, I believe proper administration of the Decision and Order will be served and facilitated by the following clarification of the December 24 Order.

In reviewing the Decision and Order and the possible need for clarification, I have not considered any new evidence or argumentation. I have sought only to discern any possible source or sources of any lack of clarity in the expression of my intentions at the time I issued the Decision and Order. Comments received from the parties have been most helpful in determining whether or not my intentions were clearly expressed. The sole purpose of this clarification is to add clarity to the expression of my intentions at the time I issued the December 24 Decision and Order.

The December 24 Order, by its terms, provides that all pesticide products containing heptachlor or chlordane for use (1) on corn pests, (2) on household, garden, lawn, and turf pests (both by private homeowners and by pesticide control operators), (3) against ticks and chiggers, and (4) as a constituent in shelf paper, are suspended [the suspension of products for use on corn having a post-effective date of August 1, 1976]. The Order further provides that any stocks of technical grade heptachlor or chlordane formulated into products intended for such uses [after July 29, 1975] may not be placed in commerce, sold, or used for such purposes *or any other purpose* not specifically exempted [in the November 18, 1974, cancellation order] *or specifically permitted in accordance with the Decision of the Administrator attached thereto.*

The uses *specifically permitted* or continued by the Decision accompanying the December 24 Order include only those set forth in paragraph 4 of the Conclusions contained in the Decision* and, therefore, these uses (together with the exempted uses for subsurface ground injection for termite control and dipping of roots or tops of nonfood plants) are the only uses *not* suspended by the December 24 Decision and Order. All other registrations for uses of products containing heptachlor or chlordane are suspended. Because the words "intended for such uses" in line 12 of the Order might be interpreted as limiting the suspended uses to the four uses enumerated in the first sentence of the Order, the words "intended for such uses" are hereby deleted from the December 24 Order.

The reasons for the specific enumeration of four uses suspended in the first sentence of the Order, while suspending uses for "any other purpose" in blanket form in the second sentence, are twofold: (1) other than an occasional reference to certain fruits and vegetables and other

* Decision of the Administrator, p. 76.

miscellaneous crops, the record (including the Recommended Decision of the Administrative Law Judge) does not adequately address many other (presumably minor) uses of heptachlor and chlordane, as to which little or no benefits evidence was presented at the hearing, and indeed, because the record was so inadequate in this regard, the Administrative Law Judge recommended that such other uses not be continued, and (2) the four uses enumerated specifically in the December 24 Order are among the uses as to which sufficient benefits evidence was presented at the hearing to permit a risk-benefit assessment. Blanket suspension of uses as to which there was little or no evidence on benefits was necessary because the evidence on carcinogenicity risk was applicable to ali uses. In view of the risk so established, and in the absence of sufficient benefits evidence as to uses for "any other purpose," it was of course necessary to suspend such other uses, even though (for the reasons indicated above) they could not be enumerated specifically in the Order.

As to the grouping of uses on "certain fruits and vegetables and other miscellaneous crops" [referred to in paragraph 5 of the Conclusions in the Decision], it was my intention that the provision in the Order applicable to uses for "any other purpose" apply as well to this grouping of uses. In stating that "the record in this proceeding is not sufficient to reach a conclusion" regarding this grouping of uses,* I stated only that the evidence on benefits was insufficient to permit the kind of discussion of the risk-benefit assessment which I had used for better documented uses. Therefore, with respect to this grouping of uses, I reached the same ultimate conclusion as discussed above concerning uses for "any other purpose" generally, *i.e.* that, in view of the evidence on carcinogenicity risk, and in the absence of sufficient benefits evidence, these uses are suspended, even though they could not be enumerated spe-

* Decision of the Administrator, p. 76.

cifically in the Order. Thus, there is no inconsistency between paragraph 5 of the Conclusions in the Decision and the provisions of the Order.

In view of the foregoing, I do not find it necessary to either adopt or reject the Proposed Order submitted by Respondent.

/s/ RUSSELL E. TRAIN
Russell E. Train

Dated: January 19, 1976

(Certificate of Service Omitted in Printing)

APPENDIX F

Statutes

Administrative Procedure Act, 5 U.S.C. § 556(d) (1970):

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

Federal Insecticide, Fungicide and Rodenticide Act of June 25, 1947, 61 Stat. 163 (1947):

§ 4. • • •

b. The Secretary, whenever he deems it necessary for the effective administration of this Act, may require the submission of the complete formula of the economic poison. If it appears to the Secretary that the composition of the article is such as to warrant the proposed claims for it and if the article and its labeling and other material required to be submitted comply with the requirements of section 3 of this Act, he shall register it.

c. If it does not appear to the Secretary that the article is such as to warrant the proposed claims for it or if the article and its labeling and other material required to be submitted do not comply with the provisions of this Act, he shall notify the registrant of the manner in which the article, labeling, or other material required to be submitted fail to comply with the Act so as to afford the registrant an opportunity to make the corrections necessary. If, upon receipt of such notice, the registrant insists that such corrections are not necessary and requests in writing that it be registered, the Secretary shall register the article under protest, and such registration shall be accompanied by a warning, in writing, to the registrant of the apparent failure of the article to comply with the provisions of this Act. In order to protect the public, the Secretary, on his own motion, may at any time, cancel the registration of an economic poison and in lieu thereof issue a registration under protest in accordance with the foregoing procedure. In no event shall registration of an article, whether or not protested, be construed as a defense for the commission of any offense prohibited under section 3 of this Act.

• • •

e. The Secretary is authorized to cancel the registration of any economic poison at the end of a period of five years following the registration of such economic poison or at the end of any five-year period thereafter, unless the registrant, prior to the expiration of each such five-year period, requests in accordance with regulations issued by the Secretary that such registration be continued in effect.

• • •

§ 6. • • •

c. The examination of economic poisons or devices shall be made in the United States Department of

Agriculture or elsewhere as the Secretary may designate for the purpose of determining from such examination whether they comply with the requirements of this Act, and if it shall appear from any such examination that they fail to comply with the requirements of this Act, the Secretary shall cause notice to be given to the person against whom criminal proceedings are contemplated. Any person so notified shall be given an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Secretary it appears that the provisions of this Act have been violated by such person, then the Secretary shall certify the facts to the proper United States attorney, with a copy of the results of the analysis or the examination of such article: *Provided,* That nothing in this Act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel proceedings minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

d. It shall be the duty of each United States attorney, to whom the Secretary or his agents shall report any violation of this Act, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States without delay.

Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Act of May 12, 1964, 78 Stat. 190 (1964), 7 U.S.C. § 135b (1970):

• • •

(c) If it does not appear to the Administrator that the article is such as to warrant the proposed claims for it or if the article and its labeling and other material required to be submitted do not comply with the provisions of sections 135 to 135k of this title,

he shall notify the applicant for registration of the manner in which the article, labeling, or other material required to be submitted fail to comply with said sections so as to afford the applicant for registration an opportunity to make the corrections necessary. If, upon receipt of such notice, the applicant for registration does not make the corrections, the Administrator shall refuse to register the article. The Administrator, in accordance with the procedures specified herein, may suspend or cancel the registration of an economic poison whenever it does not appear that the article or its labeling or other material required to be submitted complies with the provisions of sections 135 to 135k of this title. Whenever the Administrator refuses registration of an economic poison or determines that registration of an economic poison should be canceled, he shall notify the applicant for registration or the registrant of his action and the reasons therefor. Whenever an application for registration is refused, the applicant, within thirty days after service of notice of such refusal, may file a petition requesting that the matter be referred to an advisory committee or file objections and request a public hearing in accordance with this section. A cancellation of registration shall be effective thirty days after service of the foregoing notice unless within such time the registrant (1) makes the necessary corrections; (2) files a petition requesting that the matter be referred to an advisory committee; or (3) files objections and requests a public hearing. Each advisory committee shall be composed of experts, qualified in the subject matter and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Administrator shall by

rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence, all of which costs may be assessed against the petitioner, unless the committee shall recommend in favor of the petitioner or unless the matter was referred to the advisory committee by the Administrator. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee. The Administrator shall forthwith submit to such committee the application for registration of the article and all relevant data before him. The petitioner, as well as representatives of the Environmental Protection Agency, shall have the right to consult with the advisory committee. As soon as practicable after any such submission, but not later than sixty days thereafter, unless extended by the Administrator for an additional sixty days, the committee shall, after independent study of the data submitted by the Administrator and all other pertinent information available to it, submit a report and recommendation to the Administrator as to the registration of the article, together with all underlying data and a statement of the reasons or basis for the recommendations. After due consideration of the views of the committee and all other data before him, the Administrator shall, within ninety days after receipt of the report and recommendations of the advisory committee, make his determination and issue an order, with findings of fact, with respect to registration of the article and notify the applicant for registration or registrant. The applicant for registration, or regis-

trant, may, within sixty days from the date of the order of the Administrator, file objections thereto and request a public hearing thereon. In the event a hearing is requested, the Administrator shall, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 1006(c) of Title 5. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided,* That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, but not later than ninety days, the Administrator shall evaluate the data and reports before him, act upon such objections and issue an order granting, denying, or canceling the registration or requiring modification of the claims or the labeling. Such order shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reason certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the order is based. In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency or with an advisory committee appointed as herein provided. Notwithstanding the provisions of section 135a(c)(4) of this title, information relative to formulas of products acquired by authority

of this section may be revealed, when necessary under this section, to an advisory committee, or to any Federal agency consulted, or at a public hearing, or in findings of fact issued by the Administrator. All data submitted to an advisory committee in support of a petition under this section shall be considered confidential by such advisory committee: *Provided,* That this provision shall not be construed as prohibiting the use of such data by the committee in connection with its consultation with the petitioner or representatives of the Environmental Protection Agency, as provided for herein, and in connection with its report and recommendations to the Administrator. Notwithstanding any other provision of this section, the Administrator may, when he finds that such action is necessary to prevent an imminent hazard to the public, by order, suspend the registration of an economic poison immediately. In such case, he shall give the registrant prompt notice of such action and afford the registrant the opportunity to have the matter submitted to an advisory committee and for an expedited hearing under this section. Final orders of the Administrator under this section shall be subject to judicial review, in accordance with the provisions of subsection (d) of this section. In no event shall registration of an article be construed as a defense for the commission of any offense prohibited under section 135a of this title.

• • •

(f) The Administrator is authorized to cancel the registration of any economic poison at the end of a period of five years following the registration of such economic poison or at the end of any five-year period thereafter, unless the registrant, prior to the expiration of each such five-year period, requests in accordance with regulations issued by the Administrator that such registration be continued in effect.

Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Act of October 21, 1972, 86 Stat. 973 (1972), 7 U.S.C. § 136d (Supp. III 1974):

(a) Cancellation after five years.

(1) Procedure.

The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

(2) Information.

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

(b) Cancellation and charge in classification.

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

(c) Suspension.

(1) Order.

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification

proceedings, he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide.

Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Agency on the question of whether an imminent hazard exists.

(2) Expedite hearing.

If no request for a hearing is submitted to the Agency within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Agency agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of Title 5, except that the presiding officer need not be a certified hearing examiner. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order.

Whenever the Administrator determines that an emergency exists that does not permit him to hold a

hearing before suspending, he may issue a suspension order in advance of notification to the registrant. In that case, paragraph (2) shall apply except that (i) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (ii) no party other than the registrant and the Agency shall participate except that any person adversely affected may file briefs within the time alloted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review.

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Petitions to review orders on the issue of suspension shall be advanced on the docket of the courts of appeals. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceeding under this section. The commencement of pro-

ceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review.

In the event a hearing is requested pursuant to subsection (b) of this section or determined upon by the Administrator pursuant to subsection (b) of this section, such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National

Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before him and issue an order either revoking his notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Judicial review.

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Act of November 28, 1975, 89 Stat. 751 (1975), 7 U.S.C. § 136d(b) (Supp. V 1975):

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread

and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provi-

sion of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secreary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c) of this section. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.

Regulations

7 C.F.R. § 364.28 (1970):

Order of proceeding and burden of proof. At the hearing, the person whose objections raised the issues to be determined shall be, within the meaning of 5 U.S.C. 556(d) (formerly 5 U.S.C. 1006(c)), the

proponent of the order sought, and accordingly shall proceed first at the hearing and have the burden of proof.

40 C.F.R. § 164.121(g) (1975):

(g) *Order of proceeding and burden of proof.* At the hearing, the proponent of suspension shall have the burden of going forward to present an affirmative case for the suspension. However, the ultimate burden of persuasion shall rest with the proponent of the registration.

Supreme Court, U. S.
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No. 76-1250

In the Supreme Court of the United States

OCTOBER TERM, 1976

VELSICOL CHEMICAL CORPORATION, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE ENVIRONMENTAL PROTECTION AGENCY IN OPPOSITION

WADE H. McCREE, JR.,
Solicitor General,
Department of Justice,
Washington, D.C. 20530.

In the Supreme Court of the United States

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-25) and its supplemental opinion on petition for rehearing (Pet. App. 26-39) are reported at 548 F. 2d 998. The decision of the Administrator of the Environmental Protection Agency (Pet. App. 136-208) is reported at 41 Fed. Reg. 7572. The recommended decision of the administrative law judge (Pet. App. 42-135) is reported at 41 Fed. Reg. 7555.

JURISDICTION

The judgment of the court of appeals (Pet. App. 40-41) was entered on November 10, 1976. A timely petition for rehearing was denied on January 6, 1977. The petition for a writ of certiorari was filed on March 8, 1977. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether, in pesticide registration suspension proceedings under the Federal Insecticide, Fungicide and Rodenticide Act, the registrant bears the burden of persuasion.

STATEMENT

1. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 86 Stat. 976, as added and amended, 7 U.S.C. (Supp. V) 136 *et seq.*, all pesticides must be registered with the Administrator of the Environmental Protection Agency. They cannot be registered unless the Administrator first determines that they meet the requirements of 7 U.S.C. (Supp. V) 136a(c)(5), among which are that the pesticides will perform their intended functions and not cause "unreasonable adverse effects on the environment."[1]

If it appears to the Administrator that a registered pesticide no longer meets registration requirements, he may: (1) cancel a registration following an opportunity for an adjudicatory hearing;[2] (2) when he deems it necessary, suspend a registration pending the outcome of cancellation

[1]"[U]nreasonable adverse effects on the environment" means "unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits." 7 U.S.C. (Supp. V) 136(bb).

[2]7 U.S.C. (Supp. V) 136d(b) provides that the Administrator may cancel the registration of a pesticide if "it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."

proceedings;[3] or (3) issue an emergency suspension order, effective on issuance, without a prior hearing. This case involves suspension of registration after a hearing, pending a final cancellation decision.

The suspension provision, 7 U.S.C. (Supp. V) 136d(c)(1), provides that the Administrator may suspend the registration of a pesticide immediately if he "determines that action is necessary to prevent an imminent hazard during the time required for cancellation." The term "imminent hazard" is defined to mean "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973." 7 U.S.C. (Supp. V) 136(*l*).

2. On December 24, 1975, the Administrator of the Environmental Protection Agency suspended most registrations of heptachlor and chlordane,[4] two chlorinated

[3]A suspension order may not be issued until after notice of intent to suspend has been given to the registrant. The notice is required to set forth "findings pertaining to the question of 'imminent hazard'," and a registrant may request an expedited hearing under 7 U.S.C. (Supp. V) 136d(c)(2). That statute provides that, after a hearing, the presiding officer has ten days to submit recommended findings and conclusions to the Administrator who, in turn, has seven days to issue a final order. 7 U.S.C. (Supp. V) 136d(c) (4) provides for expedited judicial review in the court of appeals of the final suspension order.

[4]Technical grade heptachlor and chlordane are complex mixtures of related chemicals. Both contain heptachlor, gamma-chlordane and nonachlor (Pet. App. 47, 48). Chlordane also contains alphachlordane (Pet. App. 47). Heptachlor can be converted to the more persistent heptachlor epoxide through oxidation in the soil and metabolism in plants and animals (*id.* at 48). Chlordane is metabolized into the more persistent oxychlordane (*id.* at 49). Neither of the chemicals, nor any of their components or metabolites, occurs naturally. Petitioner is their sole manufacturer (*id.* at 43).

hydrocarbon pesticides[5] (Pet. App. 136-202). Based upon the evidence that these chemicals found their way into the food supply, and that they created a significant risk of cancer (Pet. App. 48-56), the Administrator determined that continuation of certain uses of the two chemicals during the time required to reach a final decision in the cancellation proceedings would create an "imminent hazard."[6] Therefore, as Section 6(c) of FIFRA, 7 U.S.C. (Supp. V) 136d(c), requires in light of this finding, the Administrator suspended those uses of the pesticides.[7]

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[5]Chlorinated hydrocarbon pesticides, which include DDT, aldrin, dieldrin, heptachlor, chlordane, endrin, and toxaphene, have been widely used. Since the 1960s the effects on man and the environment of these chemicals have been the subject of intense concern. See Department of Health, Education, and Welfare, *Report of the Secretary's Commission on Pesticides and their Relationship to Environmental Health* 470-478 (1969). On June 14, 1972, the Administrator cancelled almost all registrations of DDT. That decision was upheld. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 489 F. 2d 1247 (C.A. D.C.). On October 1, 1974, the Administrator suspended the major uses of aldrin and dieldrin. That order also was affirmed. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 510 F. 2d 1292 (C.A. D.C.).

[6]The Administrator's findings and conclusions (Pet. App. 136-208) were based on the record developed at the 43-day adjudicatory hearing. The issues at that hearing were limited to three areas of concern: (1) the human cancer risk posed by pesticidal uses of heptachlor and chlordane; (2) the contamination levels of man and his food supply as established by tissue levels and food residues; and (3) the benefits of the registered uses, with particular emphasis on the availability of alternatives. 40 Fed. Reg. 34456.

[7]The Administrator suspended all heptachlor and chlordane registrations for household lawn, garden, and turf uses, use to control ticks and chiggers, and all agricultural uses, with a limited number of exemptions. These exempted agricultural uses include heptachlor as a seed dressing and for application on Hawaiian pineapples, and chlordane for control of cutworms on corn (until August 1, 1976), white-fringed beetles in eight Southern states, strawberry pests, root weevils in Florida citrus, and white grubs in Michigan. Nonagricultural uses which were not suspended include heptachlor on narcissus bulbs and chlordane in federal and state quarantine programs for control of fire ants, control of black vine weevils in Michigan, and control of harvester ants in Oklahoma (Pet. App. 199-201).

3. Petitioner sought judicial review, arguing that the Administrator's findings concerning cancer in mice and rats are unsupported by substantial evidence. Petitioner also argued that heptachlor and chlordane are not animal carcinogens at low dose levels and that the amounts of these chemicals to which humans are exposed are too small to be a cancer hazard. Finally, petitioner argued that the Administrator has the burden of showing that substances pose an imminent danger to human health.[8]

The court of appeals upheld the Administrator's decision in all pertinent respects. It first explained that the registrant of a pesticide has the burden of demonstrating that it should continue to be in use (Pet. App. 8-9) and that, once the Administrator determines that a pesticide creates a risk of cancer, he should suspend the registration unless there is strong evidence that the economic benefits of the pesticide outweigh that risk (*id.* at 11). The court concluded that laboratory studies establish that chlordane and heptachlor are carcinogens and that their persistence makes them dangerous to man (*id.* at 12-24). Consequently, the court sustained the suspension.[9]

Petitioner sought rehearing, arguing that the court of appeals' decision concerning burdens of proof was mistaken. The court of appeals denied the petition for rehearing. It first reiterated its conclusion that the Administrative Procedure Act's provision with respect to burdens

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[8]The Environmental Defense Fund (EDF) and the Secretary of Agriculture also petitioned for review. EDF contended that the Administrator had not justified his decision not to suspend some uses of the pesticides and had not explained his decision to permit use of existing stocks. The Secretary argued that benefits of continued use outweighed the risks.

[9]The court of appeals upheld the Administrator's decision not to suspend the registration of heptachlor and chlordane with respect to certain limited uses (Pet. App. 24-25).

(5 U.S.C. 556(d)) pertains to the burden of coming forward with evidence but does not govern the burden of persuasion. The court held that, in any event, that provision does not govern when a different burden is "otherwise provided by statute," and FIFRA provides that the burden of persuasion is borne by the registrant of the pesticide (Pet. App. 33-39).

ARGUMENT

Petitioner contends that this case presents important issues concerning the allocation of burdens of proof and persuation under Section 7(c) of the Administrative Procedure Act, 5 U.S.C. 556(d). It does not. Section 7(c) explicitly states that it applies only when the burden of proof is not "otherwise provided by statute." In the present case the court of appeals concluded that FIFRA is a statute containing its own rules with respect to burdens of proof (Pet. App. 33-39). The court of appeals' discussion of the allocation of burdens under Section 7(c) therefore is *dicta*, and this case is controlled entirely by FIFRA.

Petitioner does not contend that there is a conflict among the circuits concerning the interpretation of FIFRA and the allocation of burdens under that statute. Indeed, petitioner concedes (Pet. 11) that in registration or cancellation proceedings under FIFRA the applicant or registrant bears the burden of persuasion. Every court of appeals that has considered the question has reached the same conclusion. See *Dow Chemical Corp.* v. *Ruckelshaus*, 477 F. 2d 1317, 1324 (C.A. 8); *Southern National Manufacturing Co.* v. *Environmental Protection Agency*, 470 F. 2d 194, 196-197 (C.A. 8); *Continental Chemiste Corp.* v. *Ruckelshaus*, 461 F. 2d 331, 335 (C.A. 7); *Stearns Electric Paste Co.* v. *Environmental Protection Agency*, 461 F. 2d 293, 303-304 (C.A. 7).[10]

[10]See also *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F. 2d 584, 593 (C.A. D.C.); *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 465 F. 2d 528, 532 (C.A. D.C.); *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 510 F. 2d 1292, 1297 (C.A. D.C.).

Petitioner contends, however, that although the registrant bears the burden in registration and cancellation proceedings, the Administrator should bear the burden in suspension proceedings. This contention is insubstantial. The Administrator has interpreted FIFRA as placing the burden in suspension proceedings upon the registrant (40 C.F.R. 164.121(g)), and this allocation is consistent with both the purposes and the language of FIFRA. As the court of appeals explained (Pet. App. 34-36), FIFRA was amended in 1964 precisely in order to ensure that doubts about the safety of pesticides would be resolved in favor of protection of health. The reports accompanying the 1964 amendments, abolishing "registration under protest," explain that the purpose of the change is to compel registrants to assume at all times the burden of demonstrating that pesticides are not injurious to human health. See, *e.g.*, H.R. Rep. No. 1125, 88th Cong., 2d Sess. 2 (1964).

The suspension proceeding is designed to allow the Administrator to make prompt decisions when he receives evidence that a pesticide poses an imminent danger to health. It would be anomalous if the registrant bore the burden in the cancellation proceeding, yet the Administrator bore the burden in a suspension proceeding that was designed to permit dangerous pesticides to be removed from the market on a temporary basis pending a final decision in the cancellation proceedings. Petitioner has not offered any cogent reason why Congress would have required the registrant to bear the burden in the cancellation proceeding but required the Administrator to bear it in a suspension proceeding.

It is true, as petitioner points out, that FIFRA was amended in 1972 to incorporate the general standards of the Administrative Procedure Act. See 7 U.S.C. (Supp. V)

136d(c). But petitioner does not point to anything in the congressional debates surrounding that amendment that tends to demonstrate that Congress thereby altered the burdens of proof that had been established in 1964. As the court of appeals explained (Pet. App. 36-37; footnotes omitted), "[i]n light of the clarity with which Congress originally undertook to fix the burden of proof (persuasion) on the registrant, and the firmness of the courts' interpretation of the 1964 amendment, we cannot believe that the general incorporation of APA standards in 1972 was intended to shift the burden of proof away from the registrant *sub silentio*."

The court of appeals correctly interpreted FIFRA. "Congress made clear that the public was not to bear the risk of uncertainty concerning the safety of a covered poison. In the absence of an equally explicit countermanding direction from Congress, we will not force the public to assume it" (Pet. App. 39).[11]

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[11]In suspension proceedings, as in cancellation proceedings, the Administrator's decision must be upheld by the courts if it is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. (Supp. V) 136n(b). The court of appeals held that the Administrator's decision is so supported (Pet. App. 12-24), and petitioner does not challenge this decision. Moreover, petitioner apparently does not contend that the Administrator's belief that petitioners bear the burden of persuasion was an essential element of his decision. Extensive evidence was introduced by the parties concerning the risks and benefits of heptachlor and chlordane. This is not, therefore, a case in which a pesticide's registration has been suspended on an otherwise inadequate record because the registrant failed to overcome a presumption in favor of suspension. To the contrary, the evidence of record favoring suspension is overwhelming. See Pet. App. 48-107. We submit, therefore, that decision on the question concerning the burdens of proof and persuasion would not be determinative of the outcome of this case; whatever the burden may be, the Administrator's decision is supported by substantial evidence and must be sustained.

CONCLUSION

The petition for a writ of certiorari should be denied.[12]

Respectfully submitted.

WADE H. MCCREE, JR.,
Solicitor General.

APRIL 1977.

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[12]The Secretary of Agriculture takes no position on whether the petition should be granted and will not file an independent memorandum in response to the petition.

Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1976

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Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF FOR RESPONDENT ENVIRONMENTAL DEFENSE FUND, INC. IN OPPOSITION

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1976

No. 76-1250

VELSICOL CHEMICAL CORPORATION,
Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

BRIEF FOR RESPONDENT ENVIRONMENTAL DEFENSE FUND, INC. IN OPPOSITION

OPINIONS BELOW

The principal and supplemental opinions of the Court of Appeals (App. 1-39)[1] are reported at 548 F.2d 998 (D.C. Cir. 1977). The decision of the Administrator of the Environmental Protection Agency (App. 136-208) is reported at 41 Fed. Reg. 7572. The recommended decision of the Administrative Law Judge ("ALJ") (App. 42-135) is reported at 41 Fed. Reg. 7555.

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[1] "App." refers to the Appendix, and "Pet." to the Petition.

JURISDICTION

The jurisdictional requisites are adequately set forth in the Petition.

QUESTION PRESENTED

Whether the registrant of a pesticide bears the burden of persuasion in suspension proceedings under the Federal Insecticide, Fungicide and Rodenticide Act.

STATUTORY PROVISIONS INVOLVED

The pertinent statutory provisions involved are set forth at App. 209-224.

STATEMENT

Petitioners seek review of a judgment of the Court of Appeals for the District of Columbia Circuit affirming an order by the Administrator of the Environmental Protection Agency ("EPA") which suspended the registrations of the pesticides heptachlor and chlordane for certain uses pursuant to § 6(c)(1) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136d (c)(1) ("FIFRA"). The Administrator's action was based upon his conclusion that the continued use of the two pesticides presented an imminent hazard of cancer to humans.

Section 3 of FIFRA provides that no pesticide may be distributed, sold or otherwise placed in commerce unless it has been registered with the Administrator of EPA. 7 U.S.C. § 136a(a). A pesticide is eligible for registration only if the Administrator determines *inter alia* that "it will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. § 136a (c)(5)(C). Registration remains in effect for five years, during which period the registrant has a continuing re-

sponsibility to submit to the Administrator any "additional factual information regarding unreasonable adverse effects on the environment." 7 U.S.C. § 136d(a)(2).

At any time prior to the 5-year automatic cancellation (at which time the pesticide may be re-registered), the Administrator may initiate proceedings to cancel the registration if he finds that the pesticide "generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b). In such a case, a person adversely affected by the notice of intent to cancel may request a public hearing. 7 U.S.C. § 136d(b). FIFRA also provides that "[i]f the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation . . . proceedings," he may issue a notice of intent to suspend the registration pending completion of the cancellation proceedings. 7 U.S.C. § 136d(c)(1). Unless the Administrator has already done so, a notice of intent to cancel must be issued at the same time. 7 U.S.C. § 136d(c)(1). The registrant may then request an expedited hearing on the issue of suspension pursuant to § 6(c)(2) of FIFRA, 7 U.S.C. § 136d(c)(2). In cases of extreme emergency, the Administrator may issue a suspension order which takes effect immediately, prior to a hearing. 7 U.S.C. § 136d (c)(3).

On November 18, 1974, citing evidence of carcinogenicity and pervasive residues of chlordane and heptachlor in the food supply and in human tissues, the Administrator issued a notice of intent to cancel the registrations of the two pesticides, which are produced by Petitioner Velsicol Chemical Corporation. For the next eight months, Petitioner and other parties engaged in prehearing conferences, informal discovery, exchanges of documents and other preparation for the commencement of cancellation hearings. On July 29, 1975, the Administrator issued a notice of intent to suspend the registra-

tions of the two pesticides pending completion of the cancellation proceeding. Pursuant to § 6(c)(1), Velsicol requested and was granted an expedited hearing which commenced on August 12, 1975 and continued for 43 non-consecutive hearing days covering a four-month period. The record was closed on December 4, 1975.

The allocation of the burden of proof at suspension hearings is governed by an EPA regulation which provides that:

> At the hearing, the proponent of suspension shall have the burden of going forward to present an affirmative case for suspension. However, the ultimate burden of persuasion shall rest with the proponent of the registration. 40 C.F.R. § 164.121(g).

The same allocation is made in hearings involving cancellation, change in classification and denial of registration. 40 C.F.R. § 164.80(a), (b).

The ALJ issued a decision on December 12, 1975, which recommended dismissal of the notice of intent to suspend. He specifically disagreed with Velsicol on the burden of proof issue, however, noting that prior agency and judicial interpretations of FIFRA had placed the burden of proof of safety upon the registrant at all times, including in suspension proceedings (App. 96). The ALJ further observed that "[it] would be strange, indeed, that the 1972 amendment to the act [which established the suspension hearing procedure] would change the cornerstone of the statute without mention." (App. 97).

On December 24, 1975, the Administrator issued an order suspending most registrations of chlordane and heptachlor. The order accepted the ALJ's findings of fact but held that his ultimate conclusion on imminent hazard was "deficient as a matter of law" because it "failed to weigh adequately the risks in relation to the benefits as required by the statute and by Agency policy." (App.

141-145). The Administrator concurred, however, with the ALJ's construction of agency and judicial precedents regarding placement of the burden of proof, emphasizing that "it is not the Agency's burden to establish the risk of harm, but rather the registrant's burden to disprove it once its safety has been called into question by a sufficient showing of probable risk." (App. 146).

Velsicol, the Environmental Defense Fund, the U.S. Department of Agriculture and several other parties to the administrative proceeding petitioned for review of the administrator's order pursuant to 7 U.S.C. § 136d(c)(4). On November 10, 1976, the Court of Appeals held that the Administrator's suspension order was supported by substantial evidence that chlordane and heptachlor were animal carcinogens and posed a cancer hazard for humans. (App. 10-16). The court also affirmed the validity of EPA's allocation of the burden of proof. In so doing, it cited prior decisions holding that FIFRA does not require the Administrator to find that a product is unsafe in order to suspend a registration since the statute places "the burden of establishing the safety of a product requisite for compliance with the labeling requirements . . . at all times on the applicant and registrant." (App. 8). The court concluded, moreover, that EPA's allocation of the burdens of proceeding and of persuasion was also consistent with the Administrative Procedure Act, 5 U.S.C. § 556(d) ("APA"). (App. 8-9). Finally, the court pointed out that acceptance of Velsicol's arguments that the Administrator must prove imminent hazard beyond a showing of substantial likelihood of harm would "effectively foreclose" interim action to protect public health or the environment while a fuller factual record is being developed in the cancellation proceeding. (App. 10).

In denying Velsicol's petition for rehearing *en banc*, the Court of Appeals on January 6, 1977 issued a Supplemental Opinion reaffirming its original view that EPA's

allocation of the burden of proof is consistent with the APA. The court held, however, that the legislative history and numerous cases construing the controlling statute, FIFRA, indicate that "this case is one where the location of the burden of proof is, in the language of the APA, 'otherwise provided by statute.'" (App. 27). It therefore reiterated that in a suspension hearing, "the burden of persuasion rests ultimately on the registrant." (App. 38).

ARGUMENT

The Court of Appeals was correct in holding that the allocation of the ultimate burden of proof in pesticide suspension cases is controlled by FIFRA, which places that burden on the registrant. (App. 27). Petitioner's characterization of this holding as an "alternate ground" (Pet. 6) misreads the Supplemental Opinion. Although the court reaffirmed its view, stated as *dicta* in both opinions, that the APA "does not preclude assignment of the burden of persuasion to the opponent of an order" (App. 27), the holding of the Supplemental Opinion is that in FIFRA suspension hearings, "the location of the burden of proof is, in the language of the APA, 'otherwise provided by statute,' 5 U.S.C. § 556(d)." (App. 27). This holding does not raise a question of federal law of sufficient magnitude to warrant consideration by this Court nor is there any conflict among the Circuits on the issue.[2]

The court's supplemental ruling on the burden of proof is entirely consistent with its initial opinion that under the statutory scheme created by FIFRA, the burden of

[2] In fact, allocation of the burden of proof was a secondary issue in the Court of Appeals and was not dispositive of the outcome of the case. The court ruled that the Administrator's finding that chlordane and heptachlor posed an imminent hazard to human health was supported by substantial evidence. Petitioner did not contest that ruling either in its petition for rehearing *en banc* or in the petition for *certiorari*.

establishing the safety of a pesticide remains at all times on the registrant. (App. 8). The *arguendo* discussion of Velsicol's APA argument, ("Assuming that the Administrator is the 'proponent' of a suspension order and is governed by § 556(d). . .") (App. 8), was not crucial to the court's conclusion that FIFRA governs the placement of the burden of proof in pesticide suspension hearings. It merely indicated the panel's view that even if § 556(d) were applicable, (the clear implication being that it is not) "EPA's allocation of burden of proof is consistent with the requirements of [that section. . .]." (App. 9). Both the legislative history and the relevant cases confirm that the court's reading of FIFRA and of the APA were correct.

I. The Decision of the Court of Appeals on the Burden of Proof Issue Was Consistent With Prior Interpretations of FIFRA and with the Legislative Intent

There is no conflict between the decision of the Court of Appeals here and its prior decisions or those of other courts of appeals on the issue of the burden of proof under FIFRA. All of the courts considering the issue have agreed that FIFRA places upon the pesticide manufacturer a continuing burden of proving that a product is safe and therefore entitled to registration. *See Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F.2d 1292 (D.C. Cir. 1975); *Environmental Defense Fund* v. *Environmental Protection Agency*, 465 F.2d 528 (D.C. Cir. 1972); *Environmental Defense Fund* v. *Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971); *Dow Chemical Co.* v. *Ruckelshaus*, 477 F.2d 1317 (8th Cir. 1973); *Southern National Manufacturing Company* v. *Environmental Protection Agency*, 470 F.2d 194 (8th Cir. 1972); *Stearns Electric Paste Co.* v. *Environmental Protection Agency*, 461 F.2d 293 (7th Cir. 1972); *Continental Chemiste Corp.* v. *Ruckelshaus*, 461 F.2d 331

(7th Cir. 1972). That burden was specifically shifted from the Secretary of Agriculture to the registrant in the 1964 amendments to FIFRA.[3]

The foregoing precedents and the absence from the legislative history of FIFRA of any contrary suggestion persuaded the court that the general incorporation in the 1972 amendments to FIFRA of APA adjudicatory hearing standards for suspension proceedings was not intended to alter radically the statutory scheme of FIFRA by shifting the ultimate burden of proof to the Administrator "*sub silentio*." The court therefore correctly concluded that FIFRA does not allocate "a burden of proof that is different for suspension hearings than for registration or cancellation proceedings." (App. 37).

Congress' intention in providing for separate suspension proceedings in 1972 is apparent from the legislative history. Prior to 1972, FIFRA provided for immediately effective suspension orders, giving the registrant only an opportunity for submission of the matter to an advisory committee and, thereafter, for an expedited cancellation hearing.[4] The 1972 provision for expedited suspension hearings, which originated in the Senate, was designed to ensure that upon issuance of a suspension notice, the registrant would have an opportunity for an adjudica-

[3] H.R. Rep. No. 1125, 88th Cong., 1st Sess. 2 (1964).

[4] In a strained effort to distinguish between suspension and other regulatory proceedings under FIFRA, Petitioner makes much of the fact that in *Stearns Electric Paste Co.* v. *Environmental Protection Agency*, 461 F.2d 293 (7th Cir. 1972), the court "conspicuously" did not place the burden of proof on the registrant in suspension proceedings. (Pet. 11). The simple reason for this omission is that before 1972, FIFRA made no provision for separate suspension hearings. The reasoning of the *Stearns* court strongly suggests, moreover, that the burden would remain on registrants even in suspension proceedings. 461 F.2d at 304-5.

tory hearing on the question of suspension, and for review of the suspension decision in the Court of Appeals.[5]

In explanation of the inclusion of a provision for expedited suspension hearings the Senate Report stated that "[t]he Committee has also provided for expedited hearings on questions of suspension so that the procedure will be analogous to cancellation."[6] No mention was made here or elsewhere in the reports or debates of any intention to shift the ultimate burden of proof to the Administrator in suspension hearings.[7]

Congress substantially amended FIFRA again in November, 1975. The previous April, the Administrator's October, 1974 decision suspending similar pesticides, aldrin and dieldrin, on the ground of carcinogenic risk to humans, had been upheld by the Court of Appeals. *See Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F.2d 1292 (D.C. Cir. 1975). Consistent with prior agency precedent and the EPA rules of practice, the burden of proof in the aldrin/dieldrin suspension hearings had been allocated to the registrant, who unsuc-

[5] The earlier House version of the bill contained no separate provision for suspension hearings and provided only for limited district court review of suspension orders. H.R. Rep. No. 92-511, 92d Cong., 1st Sess. 22 (1971).

[6] S. Rep. No. 92-838, 92d Cong., 2d Sess. 13 (1972). Cancellation proceedings were adjudicatory and conducted pursuant to APA standards although the burden of persuasion was allocated to the registrant. At the time of the 1972 amendments, the validity of this allocation of burden had been upheld by several courts of appeals. *See*, pre-1973 cases cited in text at p. 7 *supra*.

[7] That both Houses were keenly aware of the placement of the burden of proving safety upon the registrant is clear from the Senate and House Reports, which reiterate that "[t]he burden of proof remains with the applicant (as in [pre-1972] FIFRA) to substantiate the claims for the pesticide by test data and otherwise to support the registration of a pesticide." S. Rep. No. 92-838, 92d Cong., 2d Sess. 20 (1972); H.R. Rep. No. 92-511, 92d Cong., 1st Sess. 20 (1971).

cessfully raised before both the ALJ and the Administrator the same arguments as Petitioner makes here.[8] The suspension decision was widely publicized, but Congress made no effort to alter EPA's allocation of the burden of persuasion, even though substantive changes were made to other provisions of § 6 of FIFRA. As this Court has stated, according to established principles of statutory construction,[9]

> A court may accord great weight to the long-standing interpretation placed on a statute by an agency charged with its administration. This is especially so where Congress has re-enacted the statute without pertinent change. In these circumstances, congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress. (footnotes omitted)

The overriding purpose of the 1972 amendments to FIFRA (which established the suspension hearing procedure) was to "regulate the use of pesticides to protect man and his environment." [10] To achieve this purpose, Congress reaffirmed its 1964 placement of a continuing burden upon pesticide registrants to establish the safety of their products. As pointed out above, the allocation of the burden of proof in suspension hearings advanced by Velsicol would completely disrupt this statutory scheme. The Court of Appeals correctly rejected such a construction because it would force the public to "bear the risk of uncertainty concerning the safety of a covered poison" (App. 38-39) contrary to the specific intent of Congress in placing that burden upon the registrant.

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[8] *In re* Shell Chemical Co., FIFRA Docket Nos. 145 *et al.*, 39 Fed. Reg. 37246, 37265, 37267, n. 27 (October 18, 1974).

[9] *National Labor Relations Board* v. *Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 274-5 (1974).

[10] S. Rep. No. 92-838, 92d Cong., 2d Sess. 1 (1972); *See also* H.R. Rep. No. 92-511, 92d Cong., 1st Sess. 14 (1971).

II. The Court's Interpretation of § 7(c) of the APA is Consistent with the Legislative History of the Provision and with Relevant Decisions Construing It

Even though this case is controlled by FIFRA and therefore falls within the exception to § 7(c) of the APA, the Court of Appeals correctly concluded that "the APA does not preclude the assignment of the burden of persuasion to the opponent of an order." (App. 27). As both of the court's opinions clearly demonstrate, the legislative history of the APA indicates beyond question that Congress in enacting § 7(c) was concerned with the burden of coming forward with the evidence rather than with the ultimate burden of persuasion (App. 8-9, 31-33). In explanation of § 7(c), the Senate Report states:

> That the proponent of a rule or order has the burden of proof means not only that *the party initiating the proceeding has the general burden of coming forward with a prima facie case* but that other parties, who are proponents of some different result, also for that purpose have a burden to maintain. S. Rep. No. 752, 79th Cong., 1st Sess. 22 (1945), *reprinted* in S. Doc. 248 at 208 (1946). (emphasis added)

The House Report repeats this explanation in identical language, and further states that "[t]he first and second sentences of the section [App. 209] therefore mean that, where a party having the burden of proceeding has come forward with a *prima facie* and substantial case, he will prevail unless his evidence is discredited or rebutted." [11]

The court concluded that if the change in the language of an early version of § 7(c) from "burden of proceeding" to "burden of proof," upon which Petitioner places so much weight (Pet. 9-10), had been deliberately in-

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[11] H.R. Rep. No. 1980, 79th Cong., 2d Sess. 34 (1946), *reprinted* in S. Doc. 248 at 270, 271.

tended to govern placement of the burden of persuasion, the Committee reports would have so indicated. (App. 33). The Committee Reports not only fail so to indicate, but they also repeatedly discuss the meaning of "burden of proof" in terms of the "burden of proceeding." In addition to the Committee reports, the court was also persuaded of the correctness of its interpretation by the 1947 *Attorney General's Manual on the Administrative Procedure Act*, which states that "[t]here is some indication that the term 'burden of proof' was not employed in any strict sense, but rather as synonymous with the 'burden of going forward.'" (App. 33).

Petitioners concede that there is no conflict among the Circuits on this issue (Pet. 6). They assert, however, that "analytical inconsistency" with prior decisions of other Circuits warrants plenary consideration by this Court. The Court of Appeals examined the cases upon which this claim was based and found not a single precedent holding that the proponent of an order *ipso facto* bears the burden of persuasion under the APA. As the court correctly observed, "most of the cases . . . appear to think of 'burden of proof' as the burden of producing evidence." (App. 29). *See N.L.R.B.* v. *Atlanta Coca-Cola Bottling Company*, 293 F.2d 300 (5th Cir.), *rehearing denied*, 296 F.2d 896 (1961); *United States* v. *Springer*, 491 F.2d 239 (9th Cir.), *cert. denied*, 419 U.S. 834 (1974); *Kirby* v. *Shaw*, 358 F.2d 446 (9th Cir. 1966).

Petitioners cite only two cases which deal at all with the burden of persuasion. The first, *Kerner* v. *Flemming*, 283 F.2d 916 (2d Cir. 1960), obliquely addresses the issue in *dicta*. The Court of Appeals properly declined to accept as precedent the Second Circuit panel's *arguendo* assumption that "an applicant [*i.e.*, proponent] for a disability pension has the ultimate burden of per-

suasion" (App. 30) because it did not govern the outcome of the case.[12]

The second case, *Old Ben Coal Corporation* v. *Interior Board of Mine Operations Appeals*, 523 F.2d 25 (7th Cir. 1975), is discussed in the Supplemental Opinion (App. 30) and directly supports the Court of Appeals' interpretation of § 7(c) of the APA. Contrary to Petitioner's assertion that *Old Ben* underscores the "continuing uncertainty" about the meaning of the burden of proof requirement of § 7(c) (Pet. 7), the case clearly demonstrates the Seventh Circuit's *en banc* conclusion that the section allocates the burden of going forward rather than the burden of persuasion in administrative proceedings. In *Old Ben*, the Seventh Circuit held that where Congress placed the primary responsibility for mine safety upon the mine operators, in a hearing contesting an imminent danger order,

> [t]he burden of proof is split, with the Government bearing the burden of going forward, and the mine operator bearing the ultimate burden of persuasion. 523 F.2d at 39.

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[12] McCormick has also pointed out that the *Kerner* case is representative of a trend confined largely to disability cases whereby the courts are employing the substantial evidence standard to impose a special burden of proof on administrative agencies distributing compensation benefits. In such cases, "reviewing courts are more concerned with the remedial, risk-spreading purposes of the statutes and the comparative inability of the claimant to present additional proof." McCormick, *Law of Evidence* 854 (2d ed. 1972). In contrast, McCormick notes that precisely the opposite trend is apparent in administrative adjudications where the activities of business respondents are tested, since manufacturers are presumed to have access to full knowledge about their products:

> As increasing weight is given to the public interest in fair dealing and in a healthier environment, we can expect further developments either imposing strict liability on certain business activities (footnote omitted) or requiring that the business establish by substantial evidence that its practices should not be prohibited. *Id.*

Thus, the case law as well as the legislative history demonstrate that the Court of Appeals correctly interpreted § 7(c) of the APA.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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PETITIONER'S REPLY MEMORANDUM

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PETITIONER'S REPLY MEMORANDUM

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1. The Environmental Protection Agency ("EPA"), in opposing certiorari in this case, invites this Court to disregard the extremely important issue presented by petitioner's first question: the construction of the burden of proof provision of the Administrative Procedure Act ("APA"). The Court of Appeals concluded that § 7(c) of that Act, 5 U.S.C. 556(d), although placing the "burden of proof" on "the proponent of a rule or order", permits the EPA Administrator to shift the

"burden of persuasion" to the party opposing the Administrator's proposed order for suspension of a pesticide registration. EPA seeks to justify its position by asserting that the court's conclusion was mere dictum. This assertion, however, is in obvious conflict with the Court of Appeals' own view of its conclusion for, in its supplemental opinion, the court refers to the decision on this issue as a holding: "As to the APA, our opinion *holds* that the 'burden of proof' it casts upon the 'proponent' is the burden of coming forward with proof, and not the ultimate burden of persuasion."[1] (Pet. App. 28, emphasis supplied).

Even if the court below had not so clearly labeled its conclusion a holding, it could in no sense be called dictum. The judgment below (Pet. App. 41), which this Court is asked to review, was entered with and predicated only upon the lower court's first opinion, in which the construction of the APA was the sole basis for the court's conclusion on the allocation of the burden. This conclusion was reconsidered in a "Supplemental Opinion" accompanying an order denying rehearing (Pet. App. 27); and, in a more elaborate discussion, the prior conclusion was expressly reaffirmed. Only in a separate part of its supplemental opinion did the Court of Appeals advance another theory: it declared, as an alternative, that even if[2] the APA would nor-

[1] See also Part II of the Court of Appeals Supplemental Opinion: "[W]e *held* in our panel opinion that § 7(c) was not intended to govern the allocation of the burden of persuasion . . . ." (Pet. App. 33; emphasis supplied).

[2] As stated by the Court of Appeals: "This conclusion [as to FIFRA] would be sound *even if* the APA, by itself, indisputably put the burden of persuasion on the proponent of suspension. It is strengthened by our *conclusion* (Part I) that the APA does not have that consequence." (Pet. App. 37, emphasis supplied)

mally place the "burden of persuasion" on the agency, suspension hearings under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. 136d(c) (Supp. V, 1975), fell within the exception in § 7(c) of the APA in which the burden was "otherwise provided by statute." The Court's decision on the proper construction of § 7(c) of the APA is no more dictum than its conclusion as to FIFRA. As this Court has said: "[W]here a decision rests on two or more grounds, none can be relegated to the category of *obiter dictum.*" *Woods* v. *Interstate Realty Co.*, 337 U.S. 535, 537 (1949). The stare decisis effect of one alternate ground is as great as the other; if *certiorari* is denied in this case, the federal agencies, the bench and the bar will treat the Court of Appeals' interpretation of the APA as authoritative. It is that effect that establishes the significance of this case.

The importance of the proper construction of the APA in allocating the "burden of proof" has not been, and cannot be, disputed by the EPA. The allocation of the "burden of proof" unquestionably has a substantial impact in determining the course of a multiplicity of administrative proceedings, affecting every facet of our society.

2. The Environmental Protection Agency attempts in a footnote to discount the importance of the allocation of the burden of proof as inconsequential herein. It flatly asserts that the "decision on the question concerning the burdens of proof and persuasion would not be determinative of the outcome of this case . . . ." (Brief for EPA 8, n.11). The claim that the result would have been the same if the EPA had proceeded on the basis that it had the "burden of proof" (per-

suasion) is pure conjecture. Neither the Administrative Law Judge ("ALJ") nor the Administrator, in holding that the burden of persuasion was on petitioner, suggested that their findings would have been the same had the burden been allocated to respondent. (Pet. App. 96-97, 145-46). To argue respondent's assertion at this juncture of the proceedings by marshalling the evidence of record and identifying deficiencies in the assessment of the evidence would only tax the patience of this Court. Suffice it to say that respondent's assertion simply ignores the fact (nowhere mentioned in EPA's brief) that this case was sufficiently close that respondent lost it at the hearing stage before the ALJ. The ALJ even after applying the burden of persuasion against Velsicol, recommended dismissal of the suspension notice.[3] Had the ALJ's findings been more favorable to petitioner because of a different allocation of the "burden of proof", the Administrator, who generally adopted the findings but refused to accept the recommendation of the ALJ, may well have reached other conclusions in assessing the benefits and risks attributable to different uses of the pesticides.[4]

[3] The ALJ found that "[w]ith respect to whether [chlordane and heptachlor] are carcinogens in laboratory animals and a potential carcinogenic risk to man . . . [w]e merely state that at this time we do not so conclude and, by reason thereof, we cannot find an imminent hazard with respect thereto." (Pet. App. 106-107).

[4] The Administrator was required to make a separate risk-benefit assessment for each registered use of the pesticides. For example, with respect to the major agricultural use of heptachlor and chlordane—the protection of corn crops against cutworm infestation—the evidence was in such comparative equipoise that the Administrator decided in Velsicol's favor for 1976 but against Velsicol for 1977. Surely it cannot be said that placing the burden

(footnote continued)

In the decision-making process, the allocation of the burden of proof is a pivotal element.[5] But this Court need not now decide whether the placement of the burden was pivotal in this case because an agency action based on an error of law must be overturned, even if the evidence arguably could have sustained the order under a different legal theory. *SEC* v. *Chenery Corp.*, 318 U.S. 80, 92, 94-95 (1943).[6] As this Court has held, "[a]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." 318 U.S. at 95.[7]

3. Finally, EPA argues that FIFRA falls within the APA's "except as otherwise provided by statute" clause. But respondent does not point to any language in FIFRA which does "otherwise provide." It ig-

differently could not have led to findings in Velsicol's favor for 1977 as well.

The fact that the allocation of the burden of proof was critical in the instant case was acknowledged recently in a public address by the chief trial attorney who had presented the case for EPA in the admininstrative proceedings. *See* Address of Jeffrey Howard, Esquire, "EPA-Heptachlor-Chlordane", 10 *et seq.*, before the Center for Continuing Education, "Seminar on the Federal Regulation of Environmental Carcinogens" (April 12, 1977). (A copy of the address has been lodged with the Clerk.)

[5] *See, e.g., Old Ben Coal Corp.* v. *Interior Board of Mine Operations Appeals*, 523 F.2d 25 (7th Cir. 1975); *Day* v. *National Transportation Safety Board*, 414 F.2d 950 (5th Cir. 1969).

[6] *See* also, *e.g.*, *SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947); *FTC* v. *Sperry & Hutchinson Co.*, 405 U.S. 233, 248-49 (1972); *Kovac* v. *Immigration & Naturalization Service*, 407 F.2d 102, 104 (9th Cir. 1969).

[7] If petitioner's contention on the burden of persuasion is upheld, the Court may of course choose to vacate and remand for new administrative findings.

nores the fact that Congress in enacting the 1972 amendments to FIFRA making suspension proceedings subject to APA standards explicitly set forth only one exception:

> "The [suspension] hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of Title 5, *except* that the presiding officer need not be a certified hearing examiner." 7 U.S.C. 136d(c)(2) (emphasis supplied).

The additional exception which EPA urges was not enacted.

Respectfully submitted,

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IN THE

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OCTOBER TERM, 1976

No. 76-1250

VELSICOL CHEMICAL CORPORATION,
Petitioner,

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

---

MOTION FOR LEAVE TO FILE MEMORANDUM IN SUPPORT OF THE PETITION AND MEMORANDUM FOR MANUFACTURING CHEMISTS ASSOCIATION AS *AMICUS CURIAE*

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1976

No. 76-1250

VELSICOL CHEMICAL CORPORATION,
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MOTION OF MANUFACTURING CHEMISTS ASSOCIATION FOR LEAVE TO FILE MEMORANDUM IN SUPPORT OF THE PETITION AS *AMICUS CURIAE*

The Manufacturing Chemists Association (MCA) respectfully moves for leave to file the attached memorandum as *amicus curiae* in support of the petition for a writ of certiorari in the above-entitled case. Consents have been received from the petitioner, the Solicitor General, and all other parties except for the Environmental Defense Fund which has refused its consent.

MCA is a voluntary, non-profit membership association of 201 chemical companies in the United States and

Canada representing over 90 percent of the production capacity of basic industrial chemicals within those countries. MCA has often represented the interests of its member companies in legislative, regulatory and judicial matters. The petitioner in this case, Velsicol, is a member of MCA.

The questions presented by Velsicol's petition—proper allocation of the "burden of proof" under former § 7(c) of the Administrative Procedure Act (5 U.S.C. § 556(d)), and whether § 6(c) of the Federal Insecticide, Fungicide, and Rodenticide Act places the "burden of proof" on a party opposing a suspension order issued pursuant to that Act—are important to the chemical industry, both in the context of pesticide regulation and generally. Many of MCA's members, like the petitioner, are engaged in the manufacture and formulation of pesticides. Moreover, the first question presented is not limited in impact to pesticide regulation alone; it is central to government oversight of various operations and products of the chemical industry, one of the most closely regulated in the United States. As more fully discussed in the attached memorandum, this question of the allocation of burden of proof under 5 U.S.C. § 556(d) of the Administrative Procedure Act is involved in proceedings affecting the chemical industry under numerous statutes. Accordingly, MCA wishes to submit its memorandum to cover an aspect of the question that is not fully treated in Velsicol's petition: the importance of the interpretation given 5 U.S.C. § 556(d) to federal administrative law in general and the regulation of the chemical industry in particular.

Accordingly, MCA respectfully requests that this Court grant leave to file the attached memorandum *amicus curiae*.

Respectfully submitted,

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IN THE

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MEMORANDUM FOR MANUFACTURING CHEMISTS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

Interest of the Manufacturing Chemists Association

The interest of the Manufacturing Chemists Association (MCA) is set forth in the foregoing motion for leave to file this memorandum in support of the petition for certiorari.

Briefly, the questions presented by the petition—particularly the allocation of the "burden of proof" under

former § 7(c) of the Administrative Procedure Act, 5 U.S.C. § 556(d)—are important to the chemical industry as a whole. Many of MCA's members, like the petitioner, are engaged in the manufacture and formulation of pesticides, but the issue is not limited to pesticide regulation. In addition, as outlined in greater detail below, the allocation of burden of proof under 5 U.S.C. § 556(d) has significant implications for proceedings under a variety of other statutes pervasively affecting the operations and products of chemical manufacturers. Accordingly, whether or not the decision of the lower court is reversed or upheld, in MCA's view it is important to have the issue definitively decided now by this Court.

Reason for Granting the Writ

The holding below—which places the "burden of persuasion" on a party challenging an agency's orders, despite express language in the Administrative Procedure Act, 5 U.S.C. § 556(d) that "except as otherwise provided by statute, the proponent of a rule or order has the burden of proof,"—raises an important question of federal law which has not been, but should be, settled by this Court.

It would be difficult to over-estimate the importance of federal administrative law and procedure to the functioning of our society. The passing of a quarter century has confirmed the accuracy of Mr. Justice Jackson's statement for this Court that "[t]he rise of administrative bodies probably has been the most significant legal trend of the last century and perhaps more values today are affected by their decisions than by those of all the courts, review of administrative decisions apart." [1] This trend continues to accelerate.

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[1] *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 487 (1952).

"The average person," Professor Davis has noted, "is much more directly and much more frequently affected by the administrative process than by the judicial process." [2] This is reflected in the volume of administrative activity; as long ago as 1963, the number of civil trials in all federal courts totalled approximately 7,000,[3] but the number of cases disposed of by federal agencies after "an oral hearing with a verbatim transcript" exceeded 80,000.[4] Today, nearly a score of independent federal agencies and dozens of bureaus and administrations within the Federal Executive Departments engage in administrative rulemaking and adjudication. The interests affected by their rules, orders and decisions affect every facet of American life from the grant of veterans' benefits to the grant of offshore oil leases.

If administrative law and proceedings are vital to the nation's governance, the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*, is an integral element of the federal administrative scheme.[5] There are literally hundreds of references in the United States Code to the APA; many statutes explicitly incorporate it in whole or in part.[6]

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[2] Davis, *Administrative Law Treatise* 7 (1958).

[3] Ann. Rep. Office of U.S. Courts, 136 (1963).

[4] Committee Print, Subcommittee on Administrative Practice & Procedure, Senate Committee on the Judiciary, 88th Cong., 2d Sess., Statistical Data Related To Administrative Proceedings, August 1964, p. 82.

[5] ". . . The outstanding single development in administrative law and in the administrative agencies of the last half-century, unquestionably, is the genesis and enactment of the Administrative Procedure Act." Williams, "Fifty Years of the Law of the Federal Administrative Agencies—and Beyond," 29 Fed. Bar J. 267, 268 (1970).

[6] *See, e.g.*, 15 U.S.C. § 766; 19 U.S.C. § 1337; 42 U.S.C. § 6212; 21 U.S.C. § 811; 29 U.S.C. § 628; 49 U.S.C. § 1672.

The questions presented by this case, of course, do not concern the entire APA. Rather, they focus upon the appropriate interpretation of one section of that statute —5 U.S.C. § 556(d), allocating the burden of proof in formal hearings required by 5 U.S.C. §§ 553 or 554. These formal hearing sections of the APA are vital and widely-used provisions; there are more than 30 explicit references in the United States Code to 5 U.S.C. § 554 alone. Moreover, APA formal hearing procedures apply to all rules and adjudications which are required by statute to be made "on the record after opportunity for an agency hearing . . . ." [7] Initial examination has turned up nearly 200 references in the United States Code to determinations on the record after opportunity for an agency hearing which may thus be subject to the "burden of proof" provisions of 5 U.S.C. § 556(d).[8] The following statutes are but a few of those many references which significantly impact MCA's members, and are thus potentially subject to the formal hearing "burden of proof" provisions of the APA:

The Consumer Product Safety Act, 15 U.S.C. § 2064(f);

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 346a(1), 348(f), 357(f), and 371(e)(3);

The Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. §§ 824(c), 875(b);

The Occupational Safety and Health Act, 29 U.S.C. § 659(c);

[7] 5 U.S.C. §§ 553(c), 554(a).

[8] Nor is the applicability of 5 U.S.C. § 556(d) limited to those federal statutes which implicitly or explicitly invoke it. This Court has held that the formal hearing provisions of the APA govern some federal administrative proceedings authorized by statutes which do not require that determination be made on the record after opportunity for an agency hearing. *Yong Yang Sung* v. *McGrath*, 339 U.S. 33, 50 (1950).

The Federal Water Pollution Control Act, 33 U.S.C. §§ 1320(c), 1342; and

The Toxic Substances Control Act, 15 U.S.C. § 2615(a).

These statutes are all of relatively recent origin, and they pervasively affect the operations and products of the chemical industry.[9]

The portion of 5 U.S.C. § 556(d) directing that "except as otherwise provided by statute, the proponent of a rule or order has the burden of proof," is a significant part of the federal administrative scheme and of the foregoing statutes. Wigmore stresses "the vital importance of the burden of proof . . ." [10] In administrative proceedings deciding close and very technical questions of economics, science, health and safety, such as those made under statutes regulating the chemical industry such as the Federal Insecticide, Fungicide, and Rodenticide Act involved in this case, and the other statutes cited above, the allocation of the "risk of non-persuasion" or "burden of persuasion" can be influential in determining the outcome of the proceeding.

Many regulations implementing the formal hearing provisions of the APA follow the plain language of the statute in allocating burden of proof. As a result of the decision below, however, it is to be expected that other agencies will follow the EPA's example and will shift the burden of proof or persuasion to parties opposing agency action in order to lessen the burden on themselves and the risk that their decisions or orders will not stand. The consequences of such a shift are serious and should

[9] The oldest of these statutes is the Federal Food, Drug, and Cosmetic Act. Its food additive section (§ 409, 21 U.S.C. § 348), which requires a showing of safety before chemicals are added to foods, was adopted in 1958. The most recent is the Toxic Substances Control Act adopted last year.

[10] 9 *Wigmore on Evidence* § 2483 at 267 (3d ed. 1940).

not be permitted without prior consideration of the matter by this Court.[11]

In short, the question presented in this case is an important one which should be decided by this Court. The issue is not only one of "importance in the administration of" the statute involved in this case.[12] It is also important to the administration of many other statutes, for large amounts of money and the fate of many applications, programs and products can turn on the proper interpretation of the burden of proof provisions of 5 U.S.C. § 556(d).[13]

Conclusion

For the reason stated here and in the petition, we respectfully submit that Velsicol's petition for a writ of certiorari should be granted.

Respectfully submitted,

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Counsel for Manufacturing Chemists Association

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[11] As more and more authority continues to be delegated to administrative and regulatory agencies with greater and greater power over all elements of the public weal, it is vital that the power delegated be exercised in accordance with the intent and command of Congress. The accountability of regulatory agencies to the public which they were created to serve is attenuated at best. To the extent that agencies are permitted to distort or ignore legislation limiting their power, even this accountability is lost.

[12] *See, e.g., United States* v. *Ruzicka*, 329 U.S. 287, 288 (1946).

[13] *See, e.g., United States* v. *Zazove*, 334 U.S. 602, 613-14 n.17 (1948).

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Respondents.

MOTION OF THE NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

TOGETHER WITH BRIEF *AMICUS CURIAE*

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MOTION OF THE NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

Pursuant to Rule 42 of the Rules of this Court, the National Agricultural Chemicals Association ("NACA") moves for leave to file a brief amicus curiae in support of the Petition for a Writ of Certiorari herein. The consent of the attorneys for respondent Environmental Defense Fund was requested but has been refused.

NACA is a non-profit organization incorporated under the laws of the State of Delaware with its principal offices in Washington, D.C. Its members, which number approximately 121, are manufacturers and formulators of pest control products employed in

agricultural production. These member companies produce and sell virtually all of the technical pesticide materials (active ingredients) and a large percentage of the formulated products registered for use in the United States.

This case presents the questions of what sort of showing must be made and by whom to establish that a pesticide should be suspended from use on the grounds that it constitutes an "imminent hazard" under section 6(c) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §136d(c) (Supp. V, 1975). The resolution of these questions is of vital interest and importance to the members of NACA and to the general public because of its impact on the availability of pesticides essential to the agricultural economy. In recent years, the Administrator has suspended most of the uses of certain pesticides of major importance. Further, the determination of the existence of a rebuttable presumption against registration ("RPAR")* is the first step in proceedings that may lead to the cancellation or suspension of a registered pesticide; and to date RPARs have been issued against at least eight additional major pesticides, and many dozens more are candidates for RPAR review. In these circumstances it is apparent that NACA's members, as well as the general public, have a compelling interest in the resolution the questions presented by this litigation as they relate to the procedures by which important pesticides can be summarily suspended from use for periods of indefinite duration.

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*See 40 C.F.R. §162.11

For the foregoing reasons, the motion of NACA for leave to file a brief amicus curiae in support of the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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IN THE

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Respondents.

BRIEF FOR THE NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

The National Agricultural Chemicals Association ("NACA") submits this brief in support of the Petition for a Writ of Certiorari herein by Velsicol Chemical Corporation ("Velsicol") to review the judgment of the United States Court of Appeals for the District of Columbia affirming the order of the Administrator of the Environmental Protection Agency ("EPA"), which reversed the order of the Administrative Law Judge ("ALJ").

QUESTIONS PRESENTED

1. Whether the burden of persuasion is separate and distinct from the term "burden of proof" as used in §7(c) of the Administrative Procedure Act ("APA"), 5 U.S.C. §556(d).

2. Whether §6(c) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §136d(c) (Supp. V, 1975), is a statute which shifts the "burden of proof" to the party opposing a suspension order.

INTEREST OF AMICUS CURIAE

NACA is a non-profit organization incorporated under the laws of the State of Delaware with its principal offices in Washington, D.C. Its members, which number approximately 121, are manufacturers and formulators of pest control products employed in agricultural production. These member companies produce and sell virtually all of the technical pesticide materials (active ingredients) and a large percentage of the formulated products registered for use in the United States.

This case presents the questions of what sort of showing must be made and by whom to establish that a pesticide should be suspended from use on the grounds that it constitutes an "imminent hazard" under section 6(c) of FIFRA. The resolution of these questions is of vital interest and importance to the members of NACA and to the general public because of its impact on the availability of pesticides essential to the agricultural economy. In recent years, the Administrator has suspended most of the uses of certain pesticides of major importance.[1] Further, the determination of the

[1] This proceeding involves the propriety of the suspensions heptachlor and chlordane. Chlordane is, or at least was, "... a

[footnote continued]

existence of a rebuttable presumption against registration ("RPAR")[2] is the first step in proceedings that may lead to the cancellation or suspension of a registered pesticide; and to date RPARs have been issued against at least eight additional major pesticides,[3] and many dozens more are candidates for RPAR review.[4] In these circumstances it is apparent that NACA's members, as well as the general public, have a compelling interest in the resolution the questions presented by this litigation as they relate to the procedures by which important pesticides can be summarily suspended from use for periods of indefinite duration.

ARGUMENT

The writ of certiorari should be here granted for at least two reasons.

1. The writ should be granted to decide the question of whether the burden of persuasion is separate and distinct from the "burden of proof" as that term is used in section 7(c) of the APA. The court below held that the burden of persuasion is separate and distinct,

leading insecticide in the United States" (Pet. App. at 57). EPA previously suspended aldrin and dieldrin. Almost twelve million pounds of aldrin were used in 1972. *EDF v. EPA*, 167 U.S. App. D.C. 71, 510 F.2d 1292, 1296 n.2 (D.C. Cir. 1975).

[2] See 40 C.F.R. §162.11.

[3] BHC, 41 Fed. Reg. 46024 (Oct. 19, 1976); Chlorobenzilate, 41 Fed. Reg. 21517 (May 26, 1976); Chloroform, 41 Fed. Reg. 14588 (Apr. 6, 1976); Compound 1080 and 1081, 41 Fed. Reg. 52792 (Dec. 1, 1976); Endrin, 41 Fed. Reg. 31316 (Jul. 27, 1976); Kepone, 41 Fed. Reg. 12333 (Mar. 25, 1976); Lindane, 41 Fed. Reg. 9816 (Feb. 17, 1977); Strychnine, 41 Fed. Reg. 52810 (Dec. 1, 1976).

[4] It has recently been reported that EPA is reviewing 69 pesticides for possible RPAR candidacy. Pesticide and Toxic Chemical News, Feb. 23, 1977, at 10-12.

and that the burden of proof includes only the burden of going forward.[5] The wide applicability of the APA to federal administrative proceedings and the significance in such proceedings of the allocation of the "burden of proof" make decision of this issue a matter of very substantial importance.

NACA supports and associates itself with the arguments advanced in the Petition for a Writ of Certiorari to the effect that under the APA the proponent of a rule or order has the burden of proof, including the burden of persuasion.[6] Of particular importance in this connection are those prior drafts of the APA itself which placed upon the proponent "the burden of proceeding,"[7] and which were superseded in the final legislation by language imposing upon the proponent the "burden of proof."[8]

2. The writ should also be granted to consider the closely related question of whether section 6(c) of FIFRA shifts the "burden of proof" to the party opposing a suspension order. In this connection it must be emphasized that section 7(c) of the APA places the burden of proof upon the proponent of a rule or order "[e]xcept as otherwise provided by statute." (emphasis added). The U.S. Court of Appeals for the District of Columbia Circuit concluded below that section 6(c) of FIFRA is such a statute which provides for a shift in the burden of proof.[9] But the Court did not base its

[5]Pet. App. at 8-10.

[6]Pet. at 7-10.

[7]S. Doc. 248, 79th Cong., 2d Sess. at 11, 158 (1946).

[8]S. Doc. 248, *supra*, at 30.

[9]Although the decision below of the D.C. Circuit on this point is not in conflict with that of any other U.S. Court of Appeals, it is not likely that any other U.S. Court of Appeals

[footnote continued]

conclusion upon any statutory language; it relied instead exclusively upon legislative history.[10] It is submitted that legislative history alone cannot constitute an adequate basis for bringing a statute within the above exception to section 7(c) of the APA.

Further, because a registrant has a maximum of 10 days notice to prepare for a suspension hearing, it is obvious that a gratuitous construction of FIFRA that also imposes the "burden of proof" upon the registrant in such a hearing is unreasonable. Such a construction can only have a substantial adverse effect on the continued availability of many major pesticides. NACA supports and associates itself with the arguments to this effect which are advanced in the Petition for a Writ of Certiorari.[11]

Finally, a construction of FIFRA which places the "burden of proof" upon the registrant in a suspension hearing is all the more unreasonable in view of the holding of the court below on what constitutes an "imminent hazard" under §6(c) of FIFRA justifying suspension of a pesticide during pending cancellation proceedings. The court below held that such an "imminent hazard" had been established where only a probable showing has been made that a pesticide causes cancer not in man but in laboratory animals, without regard to the extremely limited extent of any exposure of man or the environment to the pesticide during

will construe this provision of FIFRA in the foreseeable future. This is so because, not only in the instant case but also in others, various petitions filed in different Circuits that have sought review of EPA suspension or cancellation orders have been consolidated in the D.C. Circuit. *EDF v. EPA*, 510 F.2d 1292 (D.C. Cir. 1975); *EDF v. EPA*, 489 F.2d 1247 (D.C. Cir. 1973).

[10]Pet. App. at 33-39.

[11]Pet. at 10-12.

cancellation proceedings.[12] If a pesticide can be suspended simply upon a showing that it *may* cause cancer not in man but in laboratory animals that are fed extremely high doses of the pesticide, the continued availability of many major pesticides may be gravely but groundlessly threatened.

Section 6(c) of FIFRA, 7 U.S.C. §136d(c), authorizes the Administrator to suspend the registration of a pesticide where he determines that "that action is necessary to prevent an imminent hazard . . . ." The term "imminent hazard" is defined in section 2(l), 7 U.S.C. §136(l), as (in relevant part); "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment . . . ." The term "unreasonable adverse effects on the environment" is defined in section 2(bb), 7 U.S.C. §136(bb), to mean: "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide."[13] Thus, the concept of "imminent hazard" depends on the concept of "unreasonable risk," which in turn depends on weighing costs and benefits.

The court below ignored this need to weigh costs and benefits. Instead it has announced that the "imminent hazard" requisite for suspension exists simply ". . . if there is *substantial likelihood* that serious harm will be experienced during the year or two required in any realistic projection of the administrative process."[14] The court cited no authority for this formulation except for

[12]Pet. App. at 12.

[13]Pet. App. at 6.

[14]Pet. App. at 9.

an unsupported dictum in one of its earlier decisions.[15] The court then stated:

> An ultimate finding in a suspension proceeding that continued use of challenged pesticides poses a "substantial likelihood of serious harm" must be supported by substantial, but not conclusive, evidence. In evaluating laboratory animals studies on heptachlor and chlordane there was sufficient "respectable scientific authority" upon which the Administrator could rely in determining that heptachlor and chlordane were carcinogenic in laboratory animals.[16]

The court below should have focused its attention on the question of whether there was substantial evidence of an "imminent hazard", rather than whether there was substantial evidence of carcinoma in laboratory animals, without regard to the extremely limited extent of any human or environmental exposure during cancellation proceedings. The court below erroneously assumed that a finding of the latter was essentially tantamount to a finding of the former.

The court reached its conclusion by misapplying EPA's "cancer principles". According to the Court:

> [T]hese principles accept the use of animal test data to evaluate human cancer risks; *consider a positive oncogenic effect in test animals as sufficient to characterize a pesticide as posing a cancer risk to man;* recognize that negative results may be explained by the limited number and sensitivity of the test animals as compared to the general human population; note that there is no scientific basis for establishing a no-effect level for carcinogens; and view the findings of benign and malignant tumors as equally significant in

[15]Pet. App. at 9, n.15.

[16]Pet. App. at 12.

> determining cancer hazard to man given the increasing evidence that many 'benign' tumors develop into cancers.[17] (emphasis added)

Although NACA disputes the validity of these "principles", the court below, in another suspension case concerning aldrin/dieldrin, upheld the "validity of extrapolation to humans from data derived from tests on animals."[18] What the court there upheld, however, was a chain of reasoning that moved from a *solid and undisputed finding of carcinogenicity in laboratory animals* to a conclusion as to a carcinogenic risk to man. Here, by contrast, there was no such finding. Here the court below held that such a finding is not necessary, and instead affirmed a determination by the Administrator that an "imminent hazard" was established simply by a probable showing that the pesticides in question were animal carcinogens. And the showing was made without regard to the extremely limited extent of any exposure of man or the environment to the pesticide during cancellation proceedings.

In the instant case, the ALJ held, as a matter of law, that a pesticide does not present an "imminent hazard" unless it is found, as a fact, that it causes cancer in some laboratory animals.[19] The ALJ declined to make any such finding. Such a finding could serve as the basis upon which a series of inferences could be made that might lead to the conclusion that there is substantial evidence of cancer risk to man, and hence that continued use of the pesticide during pending cancellation proceedings would constitute an "imminent

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[17]Pet. App. at 13.

[18]*EDF v. EPA*, 167 U.S. App. D.C. 71, 78, 510 F.2d 1292, 1299 (1975).

[19]Pet. App. at 106-107.

hazard." But without that finding, such a series of inferences is without foundation, and any ultimate conclusion of cancer risk to man is not suppoted by *substantial* evidence. The Administrator ruled to the contrary: he held, as a matter of law, that a finding that a pesticide is carcinogenic in laboratory animals is not necessary, and his decision was affirmed by the court below. That ruling is erroneous. "[A]n administrative order cannot be upheld unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." *SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943).

In effect, then, the court below not only has erroneously placed the burden of proof in suspension proceedings upon the registrant, but also has erroneously defined the quantum of proof required to establish that continued use of a pesticide during cancellation proceedings constitutes an "imminent hazard." Unless reversed, this holding below could have serious consequences on the continued availability of many important pesticides.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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